American Recovery and Reinvestment Act of 2009, Title XIII - Health Information Technology, Subtitle B—Incentives for the Use of Health Information Technology, Section 3012, Health Information Technology Implementation Assistance

Health Information Technology Extension Program: Regional Centers Cooperative Agreement Program

Funding Opportunity Announcement and Grant Application Instructions

Office of the National Coordinator for Health Information Technology

Department of Health and Human Services

American Recovery and Reinvestment Act of 2009 Health Information Technology Extension Program: Regional Centers

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OPPORTUNITY OVERVIEW

Department of Health and Human Services (HHS)

Office of the National Coordinator for Health Information Technology (ONC)

Funding Opportunity Title: American Recovery and Reinvestment Act of 2009, Health

Information Technology Extension Program: Regional Centers

Announcement Type: New Competitive Program
Funding Opportunity Number: EP-HIT-09-003

Catalog of Federal Domestic Assistance (CFDA) Number: 93.718

Key Dates and Submission Information: The application review and funding process will be separated into three application cycles, the dates of which are outlined in the table below. Applicants will be required to submit a preliminary application that will undergo an objective review; successful preliminary applicants will be requested to submit a full application for merit review. Successful full applications will result in award of four-year cooperative agreements. Initial award decisions for Regional Centers are anticipated to be made in the first quarter of FY2010. Additional awards are expected to be made as a result of two subsequent application cycles to be completed in FY2010.

Initial Cycle	Approx Funding	Preliminary Application	Preliminary Approval	Full Applications	Awardee Selection
1	\$189,000,000	September 8, 2009	September 29, 2009	November 3, 2009	December 11, 2009
2	\$225,000,000	December 22, 2009	January 19, 2010	March 2, 2010	April 27, 2010
3	\$184,000,000	June 1, 2010	June 22, 2010	August 3, 2010	September 28, 2010

I. Funding Opportunity Description

Background

On February 17, 2009, the President signed the American Recovery and Reinvestment Act of 2009 (ARRA). Title XIII of Division A and Title IV of Division B of ARRA, together cited as the Health Information Technology for Economic and Clinical Health Act (HITECH Act), include provisions to promote meaningful use of health information technology to improve the quality and value of American health care. The HITECH Act also established the Office of the National Coordinator for Health Information Technology (ONC) within the U.S. Department of Health and Human Services (HHS) as the principal federal entity responsible for coordinating the effort to implement a nationwide health information technology (health IT) infrastructure that allows for the use and exchange of electronic health information in electronic format.

The HITECH Act (Title IV in Division B of ARRA) authorizes incentive payments for eligible Medicare and Medicaid providers' meaningful use of certified electronic health record (EHR) technology. In 2015, providers are expected to have adopted and be actively utilizing an EHR in compliance with the "meaningful use" definition or they will be subject to financial penalties under Medicare (per Sections 4101(b) and 4102(b) of ARRA). The detailed criteria to qualify for meaningful use incentive payments will be established by the Secretary of HHS (hereafter referred to as the Secretary) through the formal notice-and-comment rulemaking process. For access to the most current publicly available information about meaningful use, please visit the Meaningful Use section of the ONC programmatic website at: http://healthit.hhs.gov/meaningfuluse.

Providers seeking to meaningfully use EHRs face a variety of challenging tasks. Those tasks include assessing needs, selecting and negotiating with a system vendor or reseller, implementing project management, and instituting workflow changes to improve clinical performance and ultimately, outcomes. Past experience has shown that robust local technical assistance can result in effective implementation of EHRs and quality improvement throughout a defined geographic area.

Section 3012 of the Public Health Service Act (PHSA), as amended by ARRA (see Appendix A), authorizes a Health Information Technology Extension Program (Extension Program). By statute, the Extension Program consists of a national Health Information Technology Research Center (HITRC), and Regional Extension Centers (Regional Centers). (For a discussion of the HITRC and its relationship to the Regional Centers, see Appendix B.1.) This funding opportunity announcement seeks applications from qualified entities to serve as Regional Centers within the Extension Program.

(For information about additional priority grant programs authorized by the HITECH Act to address critical, short-term prerequisites to achieving the vision of a transformed health system where every American benefits from secure, interoperable EHRs, see Appendix B.2.)

Purpose

The purpose of the Regional Centers is to furnish assistance, defined as education, outreach, and technical assistance, to help providers in their geographic service areas

select, successfully implement, and meaningfully use certified EHR technology to improve the quality and value of health care. Regional Centers will also help providers achieve, through appropriate available infrastructures, exchange of health information in compliance with applicable statutory and regulatory requirements, and patient preferences. The support for health information exchange that is provided by Regional Centers will also be consistent with any applicable State Plan(s) for HIE developed and HHS-approved via the cooperative agreements issued by ONC pursuant to PHSA Section 3013, as added by ARRA.

Pursuant to requirements of the HITECH Act, priority shall be given to providers that are primary-care providers (physicians and/or other health care professionals with prescriptive privileges, such as physician assistants and nurse practitioners) in any of the following settings:

- individual and small group practices (ten or fewer professionals with prescriptive privileges) primarily focused on primary care;
- public and Critical Access Hospitals;
- Community Health Centers and Rural Health Clinics; and
- other settings that predominantly serve uninsured, underinsured, and medically underserved populations.

A practice otherwise meeting the definition of individual or small-group physician practice, above, may participate in shared-services and/or group purchasing agreements, and/or reciprocal agreements for patient coverage, with other physician practices without affecting its status as individual or small-group practice for purposes of the Regional Centers.

In any given Regional Center's service area, some priority primary-care providers (as described above) may have already acquired and/or implemented EHR technology. Such providers remain priority providers, though the technical assistance required is anticipated to be focused on movement from having an EHR to achieving all aspects of meaningful use of EHR technology, including but not necessarily limited to electronic exchange of health information and reporting of quality measures using the EHR.

The ultimate measure of a Regional Center's effectiveness will be whether it has assisted providers in becoming meaningful users of certified EHR technology. It is expected that each Regional Center will provide federally supported individualized technical assistance to a minimum of 1,000 priority primary-care providers in the first two years of the four-year cooperative agreement project period and that over those same two years the entire cohort of Regional Centers will, in the national aggregate, support over 100,000 priority primary-care providers to achieve successful adoption and meaningful use of certified EHRs.

Project Structure

1. Approach

Regional Centers

To enable priority primary-care providers throughout the nation to move rapidly,

effectively and efficiently towards the objective of achieving meaningful use of certified EHRs, ONC will identify through merit-based selection a cohort of applicants qualified to serve as Regional Centers. Successful recipients will form a collaborative learning network (consortium) that is facilitated by the HITRC. Lessons learned by all Regional Centers about effective practices in provider implementation and use of EHRs, and in supporting priority primary-care providers, will be shared through the HITRC across Regional Centers and with the public.

Regional Centers will be selected and awarded in three application cycles completed in FY2010. Successful full applications from each cycle will result in four-year cooperative agreements. Each cycle will require preliminary applications, objective review of the preliminary applications, full applications, merit review of the full applications, program awards and funding. A detailed description of the required content of the preliminary application and full application is included in section IV. Detailed information on application cycles and their respective preliminary and final application submission deadlines are included in section IV, below.

It is anticipated that the first cycle of awards will result in four-year cooperative agreements with at least one successful applicant furnishing services within each of the ten HHS/CMS Regions (for a map showing these regions, please see either: http://www.hhs.gov/about/regionmap.html or

http://www.cms.hhs.gov/RegionalOffices/99_RegionalMap.asp). For the second and third award cycles, the HITRC and recipients from the first cycle will provide educational resources, technical assistance, and networking opportunities to support successful applications for Regional Centers in new geographic service areas. This will ensure geographic diversity, regional collaboration, and the broadest possible national coverage of the Extension Program.

Each cooperative agreement will consist of a four-year project period with two separate two-year budget periods. Non-competing continuations for the second two-year budget period will be contingent upon performance and a determination by HHS that such continuation of the cooperative agreement with a given center is in the best interest of the program.

2. Scope of Services

Each Regional Center will plan and implement the outreach, education, and technical assistance programs necessary to meet the objective of assisting providers in its geographic service area to improve the quality and value of care they furnish by attaining or exceeding meaningful use criteria established by the Secretary. On-site technical assistance will be a key service offered by the Regional Centers to priority primary-care providers, and will represent a significant portion of the Regional Centers' activities. Regional Centers are expected to work with both priority primary-care providers who have not yet adopted EHR systems, and with priority primary-care providers who have existing EHR systems, to assist them in achieving meaningful use of certified EHR technology.

The specific scope of service all Regional Centers will be required to provide is outlined below:

• Education and Outreach to Providers – The Regional Centers will provide for

dissemination of knowledge about the effective strategies and practices to select, implement, and meaningfully use certified EHR technology to improve quality and value of healthcare. At a minimum, this support should consist of materials designed to be widely and rapidly disseminated, both for provider self-study and for use by other Regional Centers. Education and outreach activities will be supported by the HITRC and the other Regional Centers.

Other education and outreach activities can include, but are not limited to: support of regional communities of practice for providers and those who support their health IT implementation; health IT training events for clinical professionals and their support staff; and instruction and assistance on using health IT to enhance the patient-provider relationship and encourage patient self-management. Training events, programs, and communities of practice may be co-sponsored with other local resources, such as (but not necessarily limited to) state and local health services oversight agencies, professional organizations, provider organizations, and consumer organizations.

• National Learning Consortium - The Regional Centers will become, upon award, members of a consortium that will be facilitated by the HITRC. All Regional Centers will be required to participate in the consortium and its activities. Regional Centers will: participate in national and host regional network meetings; use the client management, tracking, reporting application furnished through HITRC to provide ongoing data to support ONC's monitoring, oversight, and continuous improvement of the Extension Program; and make tools and materials developed using funding provided through the cooperative agreement available for sharing with other Regional Centers, interested stakeholders, and the public, directly and/or via the HITRC. Regional Centers may also host national and/or regional meetings as appropriate. Materials that shall be shared include templates, guides, curricula, model contracts, and other informational, educational, outreach, and implementation support products.

ONC and the HITRC will assist the Regional Centers in the fulfillment of these activities through operational support, including provision of information and materials (e.g., sample contracts, workflow templates, marketing materials, privacy/security guidelines, quality improvement curriculum), networking support (e.g., online and in-person forums to support sharing between and among Regional Centers), and policy support (e.g., advice on approaches to regulatory enablers or barriers).

• Vendor Selection & Group Purchasing - This includes assistance in assessing the health IT needs of priority primary-care providers, and selecting and negotiating contracts with vendors or resellers (of EHR systems, hardware and network infrastructure, and IT services). Regional Centers should assist providers in holding vendors accountable for adhering to service level agreements.

Regional Centers are expected to design group purchasing plans to leverage volume discounts and assure a high level of service for their providers. Support should specifically focus on helping providers select the highest-value option, defined as that which offers the greatest opportunity to achieve and maintain meaningful use of EHRs and improved quality of care at the most favorable cost

of ownership and operation, including both the initial acquisition of the technology, cost of implementation, and ongoing maintenance and predictable needed upgrades over time.

Each Regional Center will offer unbiased advice on the systems and services best suited to enable the priority primary-care providers to become meaningful users of EHRs. Regional Centers will avoid entering into business arrangements creating an actual or apparent conflict of interest with the Regional Center's obligation to act solely in the best interests of advancing meaningful use of certified health IT by the providers it serves. Regional Centers that choose to offer group purchasing of EHR software, IT support services, and/or hardware must provide a choice of offerings. The selection process for these vendors must be open and competitive; the selection committee must include representatives of the priority primary-care providers actively practicing within the Regional Center's geographic service area.

- Implementation and Project Management Regional Centers must provide end-to-end project management support over the entire EHR implementation process, including individualized and on-site coaching, consultation, troubleshooting, and other activities required to assure that the supported provider is able to assess and enhance organizational readiness for health IT, assess and remediate gaps in IT infrastructure, configure the software to meet practice needs and enable meaningful use, ensure adequate software training for all staff, and track and adhere to implementation timelines.
- Practice and Workflow Redesign Regional Centers must provide support for practice and workflow redesign necessary to achieve meaningful use of EHRs. This support will require working with the priority primary-care providers, and their EHR vendor(s), to implement and troubleshoot the use of the EHR system for the consistent documentation of essential clinical information in structured format, instituting electronic administrative transactions, electronic prescribing, electronic laboratory ordering and resulting, sharing key clinical data across practice settings, providing patient access to their health information, public health reporting, and policies and practices that protect the privacy and security of personal health information. Regional Centers must be capable of mapping and redesigning work processes, updating roles and responsibilities for clinicians and support staff, and leading continuous quality improvement activities involving rapid cycle feedback.
- Functional Interoperability and Health Information Exchange Regional Centers will assist priority primary-care providers in connecting to available health information exchange infrastructure(s), including local health information exchange organizations and state-based shared utilities or directory services in compliance with applicable statutory and regulatory requirements, patient preferences, and the State Plans for health information exchange (HIE) developed and HHS-approved under cooperative agreements issued by ONC pursuant to Section 3013 of the PHSA as added by ARRA. Regional Centers will focus on meeting the functional interoperability needs of practices, including, but not limited to the electronic exchange of administrative transactions, laboratory orders

and results, medication prescriptions, quality and public health reports, patient summaries, and the information required to ensure continuity across the spectrum of care.

- Privacy and Security Best Practices Regional Centers will support providers
 in implementing best practices with respect to the privacy and security of personal
 health information, including: implementation and maintenance of physical and
 network security, user-based access controls, disaster recovery, encryption and
 storage of backup media, human resources training and policies; and
 identification of state laws and regulatory requirements that impact privacy and
 security policies for electronic interoperable health information exchange.
- **Progress Towards Meaningful Use** The Regional Centers' personnel shall participate in program training and be able to provide their clients effective assistance in attaining meaningful use. Participation in this training will also assure that the educational and informational offerings to providers in the centers' geographic areas are accurate and aligned with, but not duplicative of, the education and outreach on the provider incentives that will be furnished to providers nationwide by CMS. Regional Centers shall review the utilization of the EHRs within their participating practices, and provide appropriate feedback and support to improve low utilization of features essential for meaningful use (e.g., electronic prescribing). Where structural, technical, or policy barriers hinder progress, the Regional Centers will work with the HITRC and local stakeholders to report to ONC the existence and nature of these barriers. Regional Centers shall also help priority primary-care providers to understand, and implement technology and process changes needed to attain meaningful use requirements and demonstrate this attainment, as defined by the Secretary through Medicare and Medicaid regulations and guidance.
- Local Workforce Support The Regional Centers will be expected to partner with local resources, such as community colleges, to promote integration of health IT into the initial and ongoing training of health professionals and supporting staff. Regional Centers may provide internship opportunities for local training programs, provide instructors for didactic programs, and use local training programs' graduates to fulfill the workforce needs of their extension activities and the implementation, maintenance, and use needs of the centers' participating providers.

The Regional Centers will be expected to leverage and undertake activities that are in synergy with, where locally available, the expertise, capability, and activities of practice networks supported by HHS and other federal agencies, including, but not restricted to the Indian Health Service (IHS), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Veterans Affairs (VA), the Department of Defense (DOD), and relevant CMS demonstration projects.

Statutory Authority

The statutory authority for grants under this Funding Opportunity Announcement is contained in Section 3012 of the Public Health Service Act (PHSA) as amended by the

American Recovery and Reinvestment Act of 2009 (Pub. L 111-5) (ARRA), and ARRA Division A.

II. Award Information

Summary of Funding

Type of Award Cooperative Agreement

Total Amount of Funding Available in FY2010 \$598,000,000

 Average Award Amount
 \$ 8,543,000

 Award Floor
 \$ 1,000,000

 Award Ceiling
 \$ 30,000,000

Approximate Number of Awards 70

Project Period Length four-year project period with two separate two-year

budget periods
Estimated Start Date

budget periods
January 15, 2010

1. Funding Description

The four-year cooperative agreements will be awarded on rolling basis, in three batches. This will allow for those who are ready to begin assisting providers in their proposed service area to do so early, while giving others time to develop their business models. ONC does not anticipate awarding any Regional Center cooperative agreement for a geographic service area overlapping any other Regional Center cooperative agreement. An applicant may propose a service area not already served by a cooperative agreement under this program that constitutes any of the following: 1) a geographic area within a state; 2) a Metropolitan Statistical Area (MSA) or other medical trading area that crosses state boundaries; 3) an entire state, including any and all MSAs and rural areas within that state; or 4) multiple contiguous states, including any and all MSAs and rural areas within those states' boundaries. For purposes of this funding opportunity announcement, "state" shall be understood to mean any of the 50 United States, the District of Columbia, Puerto Rico, the US Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. For service areas in or including the territories, contiguous will be understood to mean within a reasonable distance. Proposals to serve one or more entire states must be accompanied by a letter of support from the Medicaid Director(s) of that state or states. ONC reserves the right to negotiate modifications to any proposed service area(s) in the best interest of the program, and thus the initial geographic service area for each regional center will be established through a collaborative process between applicants and HHS.

All applicants will be required to submit, by the applicable due date, a preliminary application in advance of completing a full application. Preliminary applications will undergo objective review based on the criteria outlined in section V. Applicants will be asked to complete a full application upon approval by ONC of the preliminary application for that cycle. (Further instructions for the full application will be provided upon approval of the preliminary application.) Each award under this Funding

Opportunity Announcement will be made for a defined geographic area that does not overlap or otherwise duplicate any other award under this Funding Opportunity Announcement. Cooperative agreements will include terms and conditions reserving the ability of ONC to negotiate during the course of the awarded project period further modifications to any regional center service area(s) in the best interest of the program.

2. Years One-Two Funding (FY 2010-2011)

In the first two years, recipients will use federal funding across two categories:

- Core Support This funding will be used for outreach and educational activities, grants and program management, local workforce support, and participation peer-learning and knowledge transfer activities facilitated by the HITRC. We anticipate an award value expected to average between approximately \$500,000 and \$750,000 per Center per year for these core activities for each of the two years of the initial budget period. This funding will be released quarterly pursuant to milestones established in each Regional Center award.
- Direct Assistance Support This funding will be used for providing direct onsite technical assistance to providers. In addition to the Core Support funding, approximately \$500 million will be allocated among the successful applicants in proportion to the numbers of priority primary-care providers to receive direct technical assistance during the initial budget period, as established in each Regional Center's award. This funding will be released quarterly based on the number of identified providers that have achieved specific milestones within the preceding quarter. In order to prioritize provision of support for providers in small practices, and in light of the greater economies of scale and internal resources of larger practices, the federal subsidy for a Regional Center's direct technical assistance to any single incorporated will be capped at the amount allocated for a practice equal to or less than ten priority primary-care providers.

The key provider-specific milestones include:

- Signed technical assistance contracts between the Regional Center and provider (with receipt of any participation fees required);
- Documentation of Go-Live status on a certified EHR, with active quality reporting and electronic prescribing;
- Meeting the meaningful use criteria established by the Secretary.

3. Biennial Evaluation

HHS/ONC is required to conduct biennial evaluations to assess project performance and progress towards the provider-specific milestones specified above. The funding will therefore be provided in two specific, two-year budget periods. Pursuant to PHSA Section 3012(c)(8), as added by ARRA, biennial evaluation will be conducted by an evaluation panel appointed by the Secretary of HHS. Each evaluation panel shall be composed of private experts, none of whom may be connected with the Regional Center involved, and of federal officials. Each evaluation panel will measure the involved Center's performance against the statutory objectives of the Regional Center program (PHSA Section 3012(c)(3), as added by ARRA) and against the performance objectives

established in the cooperative agreement, including participation in the National Learning Consortium and progress towards the provider-specific milestones above. This assessment will place significant emphasis on the proportion of priority primary-care providers receiving direct technical assistance that were able to achieve successful adoption and meaningful use of certified EHR systems. A Regional Center may receive continued federal support in the third and fourth year (the second of the 2-year budget periods) of the four-year cooperative agreement, if findings of its overall biennial review are overall positive.

4. **Years Three-Four Funding (FY 2012-2013 Continuation)**

From the outset of the four-year project period, the cooperative agreement must include, and the recipient must implement, a plan to build a direct technical assistance infrastructure that will become self-sustaining by the end of the cooperative agreement's second year. This will depend on the Regional Center's ability to demonstrate value to the provider community in the first two years of the program. It is expected that the direct technical assistance functions of the Regional Centers will be entirely self-sustaining for providers eligible to receive health IT meaningful use incentive payments for 2011 and following years.

Therefore, federal support in years three and four is expected to be limited to core activities (e.g., participation in the communities of practice and other peer-learning and knowledge transfer activities facilitated by the HITRC).

ONC reserves the right to redistribute any direct assistance funds awarded for years one and two that remain unobligated by the awardee; or to negotiate an expansion of the service area of Regional Centers to surrounding areas not otherwise supported, in years three and four.

Type of Award

Awards will be in the form of a four-year cooperative agreement with each Regional Center. Under this type of award, ONC will work with each Regional Center in a collaborative way to develop and implement activities, including multi-stakeholder partnerships that will deliver efficient and effective outreach, education and, technical assistance to the providers in the region the Regional Center serves. Recipients will be required to track progress by collecting specific, standardized data about their Regional Centers' activities and progress toward milestones. Cooperative agreements are a type of Federal assistance that involves a substantial level of government participation in funded activities. Under the cooperative agreement, ONC requires that certain activities be planned jointly and include approval from ONC. Because these awards are cooperative agreements, continuation of funding will also be contingent on recipients' full participation in collaborative activities.

Further guidance regarding the requirements of the award will be furnished by ONC to the applicants invited by ONC, as a result of objective review of the applicants' preliminary applications, to submit a final application. This guidance will also be published by ONC via applicable websites, including http://healthit.hhs.gov, and other mechanisms to assure it is broadly available to the public.

III. Eligibility Information

Eligible Applicants

Any entity submitting a preliminary application for this award must be a United Statesbased nonprofit institution or organization, or group thereof. Proof of nonprofit status is required.

Cost-Sharing

Based on an assessment of current national economic conditions, the Secretary of HHS is waiving the 50 percent limitation on HHS funding for annual capital and operating and maintenance funds needed to establish and maintain a Regional Center. In place of these funding requirements, the Secretary has structured the funding partnership between HHS and the recipient as indicated below.

This partnership both reflects HHS experience with start-up activities associated with these complex endeavors and the HHS's projection that —once up and operating—Regional Centers may be receiving fees for the services and support they will be providing to providers in their geographic areas. We anticipate that this program income will be substantial for all successful projects. This program income is an allowable source of the recipients' share in the following table. The application shall include a sustainability plan clearly setting out the recipient's strategy to achieve sustainability by the end of the year two of the four-year cooperative agreement.

The funding partnership is as follows:

HEALTH IT REGIONAL CENTERS FUNDING-PARTNERSHIP SUMMARY			
YEAR	FEDERAL AMOUNT OF COSTS	RECIPIENT AMOUNT OF COSTS	
1	90 percent	10 percent	
2	90 percent	10 percent	
3	10 percent	90 percent	
4	10 percent	90 percent	

Please see Appendix C for information on calculation of cost share.

It is expected that Regional Centers will generate resources to support cost sharing in ways that demonstrate provider and community commitment to the center and its goals of supporting adoption and meaningful use of health IT. Such sources of funding to support the center's cost share obligation under the cooperative agreement could include perprovider participation fees. This statement does not preclude recipients using other legal sources of cost sharing contributions as governed by 2 CFR Part 215.

Fees and other funds generated by the project are considered program income under 2 CFR Part 215. Program income generated by the recipient shall be retained by the recipient and first used to finance the non-federal share of the project. To support sustainability, ONC places no limits on the accrual of program income. After the federal cost sharing requirement is met, program income generated shall be added to funds committed to the project by the federal government and used to further eligible project or program objectives. In other words, all funds generated using federal funds, including fees for services, will be used to meet the cost sharing requirement of the program. All funds generated after that requirement is met can be retained by the recipient and used for the same purposes for which the project was funded.

Screening and Responsiveness Criteria

1. Preliminary Application Screening Criteria

This section outlines administrative criteria that are required of all applicants. Preliminary applications will not move forward unless these screening criteria are met.

- The applicant submits a complete and timely preliminary application.
- Preliminary application demonstrates eligibility requirements addressed in section III A, Eligible Applicants.
- Preliminary application includes responses to all required questions in section IV
 B, with numeric responses where specified.
- If the applicant chooses to use the suggested template provided in Attachment 1, no additional attachments will be considered. If the applicant chooses not to use the preliminary application suggested template, the preliminary application must include all of the information in the template and shall not exceed three pages.
- The page limit excludes letters of support from stakeholders in the service area, and the State Medicaid Director(s) letter of support (suggested format is provided in Appendix D) that is required for each application proposing a Regional Center geographic service area covering an entire state or multiple states.

2. Preliminary Application Responsiveness Criteria

This section outlines content criteria that are required of all applicants.

- For any full-state or multi-state application, the applicant submits a letter from the State Medicaid Director(s) (suggested format is provided in Appendix D).
- Applicant proposes to serve a minimum of 1,000 priority primary-care providers over the initial two year budget period. The number of providers to be served must represent at a minimum 20 percent of the total primary-care providers in the proposed service area.
- Applicant proposes to serve a geographic area for which no Regional Center

3. Full Application Screening Criteria

This section outlines administrative criteria that are required of all applicants. Full applications will not move forward unless these screening criteria are met.

- The applicant has received a formal request from ONC to submit a full application for the specified geographic service area.
- The applicant meets eligibility requirements addresses in section III A, Eligible Applicants.
- The applicant submits a complete and timely full application.
- Project Narrative does not exceed 30 double-spaced pages. The 30-page limit excludes resumes, letters of support, sustainability plans, program abstract, and other attachments.

4. Full Application Responsiveness Criteria

This section outlines content criteria that are required of all applicants.

- One of the principal goals of the applicant organization is to promote the use of health IT to improve health care quality and efficiency through the authorized and secure electronic exchange and use of health information.
- The applicant certifies that it has adopted nondiscrimination and conflict of interest policies that demonstrate a commitment to transparent, fair, nondiscriminatory, and unbiased service to its geographic service area.

IV. Preliminary and Full Application Submission Information

Address to Submit Preliminary Application

Application materials will be available for download at http://www.grants.gov. ONC is requiring preliminary and full applications for all announcements to be submitted via electronic mail to regional-center-applications@hhs.gov. Applicants will be able to download a copy of the application packet, complete it off-line, and then submit the application electronically via email to: regional-center-applications@hhs.gov.

<u>PRELIMINARY APPLICATIONS</u> WILL NOT BE ACCEPTED THROUGH ANY WEBSITE, AND WILL NOT BE ACCEPTED THROUGH PAPER MAIL, COURIER, OR DELIVERY SERVICE.

APPLICANTS ARE STRONGLY ENCOURAGED TO COMPLETE AND SUBMIT APPLICATIONS AS FAR IN ADVANCE OF THE SUBMISSION DEADLINE AS POSSIBLE. THE APPLICATION INCLUDING ALL REQUIRED ATTACHMENTS AND INCLUDED FILES FOR POTENTIAL CONSIDERATION IN THE REVIEW PROCESS MUST BE RECEIVED BY 11:59 PM EASTERN TIME ON THE DATE

SPECIFIED IN SECTION IV E, BELOW.

Preliminary applications procedures:

- You must access the electronic application for this program via http://www.grants.gov. You must search the downloadable application page by the Funding Opportunity Number (EP-HIT-09-003) or CFDA number (93.718).
- All applicants should have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number and register in the Central Contractor Registry (CCR). You should allow a minimum of five days to complete the CCR registration. Although not required to process preliminary applications, applicants who do not already have a DUNS number and/or are not registered in CCR should do so as soon as possible. As there is no fee to complete these processes, applicants should not wait to receive the results of the preliminary application review before taking these steps.
- You must submit all documents electronically, including all information included on the SF424 and all necessary assurances and certifications.
- Your application must comply with any page limitation requirements described in this Funding Opportunity Announcement.
- After you electronically submit your application, you will receive an automatic email notification from the email address that demonstrates the email was received. This notification does *not* provide assurance that your application was complete, only that the email was received.
- After ONC reviews your email submission, a return receipt will be emailed to the applicant contact indicating the files that were received and able to be successfully opened and read. Due to volume of applications received, this receipt may not be available for several days; applicants are strongly encouraged to submit applications as far in advance as possible if they wish to receive confirmation of receipt prior to the deadline. Organizations applying for federal grants will need to be registered with the Central Contractor Registry (CCR). You can register with the CCR online and it will take about 30 minutes (http://www.ccr.gov). If you have already registered with CCR but have not renewed your registration in the last 12 months, you will need to renew your registration at http://www.ccr.gov.

Key Contact for all Preliminary Application:

Inquiries should be addressed to:

U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Email: regional-center-applications@hhs.gov

Preliminary Application Content Requirements

Applicants are required to submit a preliminary application to apply for this funding opportunity according to the dates specified in section IV D. This preliminary application requires the following:

- A letter signed by the designated authorized representative of that organization committing to that application, which includes the organizational mission statement.
- Proof of the applicant's nonprofit status.
- If the proposal is on behalf of a consortium, there must be letters of commitment from all members of the consortium which include their tax status.
- Any letters of support.
- A certification that there is no conflict of interest, real or perceived, with HIT vendors (See Appendix E, Conflict of Interest Certification Template).
- A letter from the State Medicaid Director(s) is required for all full-state or multistate application.
- A table or spreadsheet that addresses all of the elements below (see Attachment I).
 All estimates provided in your spreadsheet will require justification in a full proposal.
- Geographic Diversity, Service Area Participation and Collaboration:
 - Detailed service area proposed (please provide list of zip-three codes, or if smaller geographic units, zip-five)
 - Estimate of the total number of primary-care providers actively practicing in service area
 - o Estimate the total number of priority primary-care providers in the service area
 - Presence of any practice networks in the service area that are supported by other federal agencies (VA, IHS, DOD, HRSA, CMS demonstrations, other) – specify names of the networks and who supports them.
 - Level of health information exchange capability in service area. (If there
 are health information organizations in the area, name them and specify
 whether they are in planning, pilot, or operational stage.)
- Proposed Service Offerings including Proposed Center Capacity: Provide
 estimates for the minimum number of primary-care providers, and the minimum
 number of individual incorporated practices, that would receive each service
 below over the two-year budget period:
 - o Group purchasing of EHR software
 - o Onsite EHR Implementation Technical Assistance
 - o Onsite Practice and Workflow Redesign
 - o Functional Interoperability and Health Information Exchange
 - Technical Assistance around federal and State Privacy and Security requirements

- Organizational Mission, Capability, and Experience as Reflected by Current Service Offerings: If the applicant (or any members of the applying consortium) is currently offering the services listed below, indicate whether the service is currently offered (Y/N), which organization is providing it, the number of Full-Time Equivalent (FTE) staff dedicated to each, and the number of practices and providers served in the 12 month interval: July 1, 2008 to June 30, 2009.
 - o Group purchasing of EHR software
 - o Onsite EHR Implementation Technical Assistance
 - o Onsite Practice and Workflow Redesign
 - o Functional Interoperability and Health Information Exchange
- Multi-stakeholder, Community, and Provider Commitment: If the applicant includes letters of support or commitment from any of the stakeholder groups below, indicate the number of independent organizations and their names.
 - o State Primary Care Association(s)
 - Health Professional Societies
 - Health Center Controlled Networks (HCCNs)
 (for more information about HCCNs, go to:
 http://www.hrsa.gov/healthit/healthcenternetworks/default.htm)
 - o State/ Local/ Tribal Public Health Agency
 - o State Medicaid Director (if applicable)
 - Health Plans
 - o Hospital Systems
 - o Community Colleges
 - o Medicare Quality Improvement Organization
 - o Other: please specify

Address to Submit Full Applications

Full applications for all announcements must be submitted electronically through http://www.grants.gov. The grants.gov registration process can take several days. If your organization is not currently registered with http://www.grants.gov, please begin this process immediately. For assistance with http://www.grants.gov, please contact them at support@grants.gov or 1-800-518-4726 between 7 a.m. and 9 p.m. Eastern Time. At http://www.grants.gov, you will be able to download a copy of the application packet, complete it off-line, and then upload and submit the application via the grants.gov website.

Applications submitted via http://www.grants.gov:

- You may access the electronic application for this program on http://www.grants.gov. You must search the downloadable application page by the Funding Opportunity Number (EP-HIT-09-002-010535) or CFDA number (93.718).
- At the http://www.grants.gov website, you will find information about submitting

an application electronically through the site, including the hours of operation. ONC strongly recommends that you do not wait until the application due date to begin the application process through http://www.grants.gov because of the time delay.

- All applicants must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number and register in the Central Contractor Registry (CCR). You should allow a minimum of five days to complete the CCR registration.
- You must submit all documents electronically, including all information included on the SF424 and all necessary assurances and certifications.
- Prior to application submission, Microsoft Vista and Office 2007 users should review the Grants.gov compatibility information and submission instructions provided at http://www.grants.gov (click on "Vista and Microsoft Office 2007 Compatibility Information").
- Your application must comply with any page limitation requirements described in this Program Announcement.
- After you electronically submit your application, you will receive an automatic acknowledgement from http://www.grants.gov that contains a grants.gov tracking number. ONC will retrieve your application form from grants.gov.
- After ONC retrieves your application form from grants.gov, a return receipt will be emailed to the applicant contact. This will be in addition to the validation number provided by Grants.gov.
- Each year organizations registered to apply for Federal grants through http://www.grants.gov will need to renew their registration with the Central Contractor Registry (CCR). You can register with the CCR online and it will take about 30 minutes (http://www.ccr.gov).

<u>FULL APPLICATIONS</u> CANNOT BE ACCEPTED THROUGH ANY EMAIL ADDRESS. FULL APPLICATIONS CANNOT BE ACCEPTED THROUGH ANYWEBSITE OTHER THAN http://www.grants.gov. FULL APPLICATIONS CANNOT BE RECEIVED VIA PAPER MAIL, COURIER, OR DELIVERY SERVICE.

APPLICANTS WHO ARE INVITED TO SUBMIT FULL APPLICATIONS ARE STRONGLY ENCOURAGED TO COMPLETE AND SUBMIT APPLICATIONS AS FAR IN ADVANCE OF THE SUBMISSION DEADLINE AS POSSIBLE. THE APPLICATION INCLUDING ALL REQUIRED ATTACHMENTS AND INCLUDED FILES FOR POTENTIAL CONSIDERATION IN THE REVIEW PROCESS MUST BE RECEIVED BY 11:59 PM EASTERN TIME ON THE DATE SPECIFIED IN SECTION IV E, BELOW.

Key Contact for all Preliminary Application:

Inquiries should be addressed to:

U.S. Department of Health and Human Services

Email: regional-center-applications@hhs.gov

Full Application Content Requirements

Applicants whose preliminary applications are approved will be notified by ONC according to the dates indicated in section IV D. This notification will include an invitation for the applicant to submit a full application for a competitive process. ONC will provide further guidance on the following areas:

1. DUNS Number

The Office of Management and Budget (OMB) requires applicants to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for federal grants or cooperative agreements on or after October 1, 2003. As part of the full application process, applicants will complete the SF 424. The DUNS number is entered on the SF 424 (For more information about completing the SF 424, see Appendix C). It is a unique, nine-digit identification number, which provides unique identifiers of single business entities. The DUNS number is free and easy to obtain.

Organizations can receive a DUNS number at no cost by calling the dedicated toll-free DUNS Number request line at 1-866-705-5711 or by using this link to access a guide: https://www.whitehouse.gov/omb/grants/duns_num_guide.pdf.

2. Project Abstract

Applicants shall include a one-page abstract (no more than 500 words) of the application. This abstract is often distributed to provide information to the public and Congress and represents a high-level summary of the project. As a result, applicants should prepare a clear, accurate, concise abstract that can be understood without reference to other parts of the application and that provides a description of the proposed project, including: the project's goal(s), objectives, overall approach (including target priority primary-care providers and significant partnerships), anticipated outcomes, products, and duration.

The project abstract must be double-spaced, formatted to $8 \frac{1}{2}$ " x 11" (letter-size) pages with 1" or larger margins on top, bottom, and both sides, and a font size of not less than 12 point.

The applicant shall place the following information at the top of the narrative abstract (this information is not included in the 500 word maximum):

- Project Title
- Service area included in the application, described via USPS zip codes: zip-three code(s) for one or more entire counties, zip-five codes for any partial-county areas included in the proposed service area.
- Applicant Name
- Address
- Contact Name

- Contact Phone Numbers (Voice, Fax)
- E-Mail Address
- Web Site Address, if applicable

3. Project Narrative

The Project Narrative must be double-spaced, formatted to 8 ½" x 11" (letter-size) pages with 1" or larger margins on top, bottom, and both sides, and a font size of not less than 12 point. The suggested length for the Project Narrative is ten to twenty pages; twenty pages is the maximum length allowed. A full application with a Project Narrative that exceeds 30 pages will not be accepted. The Sustainability Plan (see IV C 4), Letters of Support and resumes of Key Personnel are not counted as part of the Project Narrative for purposes of the 30-page limit, but all of the other sections listed below are included in the limit.

The Project Narrative is the part of the application that will offer the most substantive information about the proposed project, and it will be used as the primary basis to determine whether or not the project meets the minimum requirements for grants under ARRA. The Project Narrative should provide a clear and concise description of your project.

(Note: a concise resource offering tips for writing proposals for HHS grants can be accessed via the Web at: http://www.hhs.gov/grantsnet/AppTips.htm)

a) Current State and Gap Analysis

Applicants are expected to complete a current analysis of the state of EHR adoption and meaningful use and determine gaps within their service areas. The applicant should propose a detailed geographic service area and the distribution of priority primary-care providers (by practice/facility type and size) to whom they will provide direct assistance. The service area will be finalized as part of the cooperative process between HHS and applicants. Considerations for HHS will include the desire for geographic diversity, as well as the:

- Number of priority primary-care providers targeted for direct assistance, and the
 proportions this number represents of the total priority primary-care and total
 primary-care providers in the proposed service area.
- Uninsured, underinsured, and medically underserved individuals as a proportion of the service area's total population.
- Number of Federally Qualified Health Centers (FQHC) and public and non-profit Critical Access Hospitals (CAH) in service area at which primary-care professionals with prescriptive privileges furnish outpatient primary-care services, and the proportion of these facilities participating.
- Partnership or collaboration with a community college or other institution of higher education offering a certificate or associates degree program(s) in health information technology or related field (please specify).
- Presence within or in close proximity to the service area of a VA hospital, DOD

medical facility, IHS or other Tribal health facility.

• Presence of organization(s) to provide for and/or infrastructure(s) providing the secure electronic exchange of health information within the geographic service area (please specify and briefly describe).

b) Provider Commitments

This section includes a list of priority primary-care providers from or for whom the applicant has signed commitment letters to use the Regional Center's direct technical assistance resources according to the terms laid out in the proposed budget. Letters may be from solo practitioners, individual practitioners within small-group practices or other prioritized settings, or authorized representatives of practices, FQHCs, or public hospitals or nonprofit CAHs. Letters must include the names and National Provider Identifier numbers of the priority primary-care providers thereby committed to use the Regional Center's services.

c) Goals and Objectives

This section includes the mission statement of the applicant's non-profit organization, and the vision, short term/long term goals and objectives that the Regional Center is using to guide its operations.

d) Proposed Strategy

This section will describe how the Regional Center plans to provide services to the priority primary-care providers as described in the section I C Scope of Services with particular attention to clarifying their understanding of the barriers faced by small practices in achieving meaningful use of certified EHR products and their approach to mitigating or eliminating these barriers through the broad support offered to all providers in the region, as well as the intensive direct assistance. This includes the following:

- Education and Training for All Providers in Service Area
- National Learning Consortium
- Vendor Selection & Group Purchasing
- Implementation and Project Management
- Practice and Workflow Redesign
- Functional Interoperability and Health Information Exchange
- Privacy and Security Best Practices
- Progress Towards Meaningful Use
- Local Workforce Support

e) Populations with Specific Needs

The Regional Center will also state how the unique needs of providers serving American Indian and Alaska Native, non-English speaking and other historically underserved populations as well as those that serve patients with maternal child, long term care, and

behavioral health needs, will be met.

f) Project Management

This describes how the Regional Center plans to govern and manage the execution of its overall program. It will include the Regional Center's governance structure, roles/responsibilities, operating procedures, composition of committees, workgroups, teams and associated leaders, and communications plans that will provide adequate planning, monitoring, and control to the overall project. The project management activities should provide details on how plans and decisions are developed and documented, issues/risks managed, and meetings facilitated.

If the applicant proposes to serve one or more entire states and/or territories, the applicant organization must demonstrate how it will effectively and efficiently provide prompt, responsive, individualized support to small practices across the entire proposed service area.

g) Core Performance Measures

This section describes how the Regional Center will achieve program outcomes assessed by quantitative performance measures, such as:

- Signed contracts with financial commitments by priority primary-care providers.
- Number of priority primary-care providers that are actively using an EHR, including active use of electronic prescribing.
- Utilization of EHRs and promoting features essential for meaningful use.
- Helping priority primary-care providers to understand, and implement technology and process changes needed to attain, and demonstrate attainment of, meaningful use requirements defined by the Secretary in applicable regulations and guidelines.

h) Evaluation

Recipients will be required to maintain information relevant to achieving the milestones specified in sections II A 2 and 4. ONC will provide for project management software for all Regional Centers to use in capturing information needed to monitor and evaluate performance. More information on the provided software and the biennial evaluation will be in program guidance by December 31, 2009.

i) Coordination and Continual Improvement

This section describes how Regional Centers will coordinate with the HITRC. This includes describing their plans for participation in regional and national network meetings, sharing experiences with barriers and solutions, use of the client management, tracking, reporting application to provide ongoing data for contract and program monitoring and evaluation purposes, and sharing of locally developed materials or tools.

This section also describes how Regional Centers will rapidly promote and disseminate knowledge about the effective strategies and practices to implement and effectively use health IT through outreach, training programs, and marketing.

j) Organizational Capability Statement

This section describes the current capability possessed by the Regional Center to organize and operate effectively and efficiently. This includes:

- 2009 Annual budget and sources of income.
- Number and roles of FTE staff in different functional areas (outreach/ communications, health IT implementation, interfaces and information exchange, hardware and network infrastructure, quality improvement, privacy and security, other).
- Identify key staff who will provide substantive work for each area covered in the Scope of Services section I C, and provide 1 page resumes for these individuals (please submit these resumes as attachments to the application).
- Previous experience with EHR implementation (number of existing vendor contracts, practices, practice sites, and providers served).
- Previous experience with workflow redesign and clinical quality improvement (number of practices, practice sites, and professional providers served).
- Previous experience with outreach, education and particularly on-site direct technical assistance in EHR adoption, implementation and appropriate use.
- Any other relevant experience that aligns with the program goals and objectives.

4. Sustainability Plan

This section describes how the Regional Center plans to maintain its services and continue to operate by the end of year two, through the remainder of the cooperative agreement period and beyond the end of the funding period. This will include local cost sharing contributions/additional funding streams, methods for achieving independent sustainability, such as payments for technical assistance and ongoing maintenance from certain non-prioritized providers who can afford services, potential assignment of payment from Medicaid providers (in the instances when the Regional Center is designated by the state as eligible to receive such assignment as an adoption entity pursuant to Section 1903(t) (1) of the Social Security Act as added by ARRA) and other potential income, such as revenue from facilitation of community-based participatory research networks.

As one aspect of achieving sustainability, applicants are encouraged to include in contracts between the Regional Center and providers a commitment of payment to the Regional Center contingent upon achievement of meaningful use criteria.

5. <u>Collaborations and Letters of Commitment from Key Participating Organizations and Agencies</u>

Coordination with other federal programs, and with related ARRA funded activities – This section describes how the Regional Centers will utilize, where locally available, the expertise and capabilities of practice networks supported by other federal agencies, such as IHS, HRSA, VA, CMS, and DOD.

Multi-Stakeholder Community and Provider Support – This section describes the various

types of support that the Regional Center plans to obtain/has already received from state primary care associations, health professional societies, HCCNs, state/local/tribal public health agencies, State Medicaid Director(s), health plans, hospital systems, community colleges, Medicare Quality Improvement Organization(s), and others relevant stakeholders.

Nondiscrimination and conflict of interest policies — This section describes the potential for any perceived conflict(s) of interest of the applicant(s), and the steps taken to demonstrate a commitment to transparent, fair, nondiscriminatory, and unbiased service to all primary care providers in the geographic service area.

6. Budget Detail

All applicants are required to outline proposed costs that support all project activities in the Budget Detail. The application must include the allowable activities with estimated costs that will take place during the funding period that will be used specifically in support of the purpose of this cooperative agreement. Costs are not allowed to be incurred until the start date listed in the Notice of Grant Award. Whether direct or indirect, these costs must be allowable, allocable, reasonable and necessary under the applicable OMB Cost Circulars: http://www.whitehouse.gov/omb/circulars and based on the programmatic requirements for administering the program as outlined in ARRA. See Appendix C for detailed information on completing the budget forms.

Awards will be made for a four-year project period with two separate two-year budget periods. In preparing the project budget, applicants should prepare these two budgets, each for two years taking into consideration the requirements of sections II A 2 and 3. For purposes of preparing the budgets, applicants should assume the following:

Core Funding

Allocate sufficient funding specifically for core activities, based on the size of the
proposed geographic service area for the Regional Center, the need for additional
capital and other costs of capacity building, and variations in locality costs, for each
year of the initial two-year budget period.

Direct Assistance Funding

- Allocate approximately one-third of the applicant's estimated total per priority primary-care provider technical assistance cost upon signed technical assistance contracts;
- Allocate approximately one-third of the applicant's estimated total per priority primary-care provider technical assistance cost upon documentation of provider's Go-Live status on a certified EHR, with active quality reporting and electronic prescribing; and
- Allocate approximately one-third of the applicant's estimated total per priority primary-care provider technical assistance cost upon provider achieving meaningful use requirements as defined by the Secretary.

Please note the following funding requirements:

Any fees received from providers are program income to be used as specified in

section III B.

- Regional Centers may be directed to use any unexpended direct assistance funds
 originally awarded for years one and two and unobligated at the end of year two for
 support of primary-care providers who are not eligible for health IT incentive
 payments (e.g., pediatricians with fewer than 20 percent Medicaid patients), or to
 expand the service area of Regional Centers.
- Additionally, the proposed budget for the first two years should reflect a recipient
 cost share of at least one dollar for every nine dollars in federal assistance. In
 preparing the budget for years three and four, the amount of recipient cost share must
 be nine dollars for every one dollar of federal assistance provided under the
 cooperative agreement.
- If proposing to serve professional providers within a single incorporated practice or other organizational provider (*e.g.* hospital or health system) including more than 10 professional providers with prescriptive privileges, regardless of their practice specialties, the amount of federally supported assistance to allocated to that practice shall not exceed the amount of assistance funding that would be allocated for 10 individual priority primary-care providers.

Submission Dates and Times

The application review and funding process will be separated into three application cycles, the dates of which are outlined in the table below. Applicants will be required to submit a preliminary application that will undergo an objective review; successful preliminary applicants will be requested to submit a full application for merit review. Successful full applications will result in award of four-year cooperative agreements. Initial award decisions for Regional Centers are anticipated to be made in the first quarter of FY2010. Additional awards are expected to be made as a result of two subsequent application cycles to be completed in FY2010.

Initial Cycle	Approx Funding	Preliminary Application	Preliminary Approval	Full Applications	Decisions to Award
1	\$189,000,000	September 8, 2009	September 29, 2009	November 3, 2009	December 11, 2009
2	\$225,000,000	December 22, 2009	January 19, 2010	March 2, 2010	April 27, 2010
3	\$184,000,000	June 1, 2010	June 22, 2010	August 3, 2010	September 28, 2010

Intergovernmental Review

This program is excluded from Executive Order 12372.

Funding Restrictions

ONC will, via program guidance, furnish potential applicants further information regarding allowable activities consistent with criteria to qualify for meaningful use

incentive payments as established by the Secretary through notice-and-comment rulemaking.

Funds under this announcement cannot be used for the following purposes:

- To supplant or replace current public or private funding.
- To supplant on-going or usual activities of any organization involved in the project.
- To purchase or improve land, or to purchase, construct, or make permanent improvements to any building except for minor remodeling.
- To reimburse pre-award costs.

Funds are to be used in a manner consistent with program policies developed by ONC. Allowable administrative functions/costs include:

- Usual and recognized overhead, including indirect rates for all consortium organizations that have a federally approved indirect cost rate; and
- Management and oversight of specific project components funded under this program.

Other Funding Information

Project Period

The four-year project period (with two separate two-year budget periods) is intended to allow recipients time to complete the goals of the application. However, applicants are strongly encouraged to plan projects and budgets that accomplish most of the federally funded project goals and milestones within the first two years of the project period.

Unobligated funds at the end of the budget/project period may be redistributed or may remain in the account for future disposition, according to ONC's determination of the best interest of the Extension Program. Unobligated funds are those reported on the annual SF-269 Financial Status Report (FSR), which is required to be submitted 90 days after the end of the budget/project period.

V. Preliminary Application and Full Application Review Information Review Criteria for the Preliminary Application

The preliminary applications will be scored according to the following evaluation criteria. For each criterion, the weighting (out of a total of 100 points) is indicated to show the relative importance.

Criterion 1: Geographic diversity, Service Area Participation and Collaboration Weight: [30 points]

• Contribution to geographic diversity of the Extension Program, including

- coverage of underserved areas.1
- Number of primary-care providers in service area
- Potential for synergy with other ONC-funded programs, including state-based health information exchange activities and future workforce training programs
- Potential for collaboration with other federal agencies

Criterion 2: Proposed Service Offerings

Weight: [20 points]

- Extent to which proposed service offerings meet the required scope for the types of service to be provided to health care providers
- Number of priority primary-care practices and providers in the service area that will be reached

Criterion 3: Organizational Mission, Capability, Experience

Weight: [30 points]

- Applicant's mission is aligned with the mission of the Extension Program
- Applicant has relevant experience and required competencies
- Applicant can meet the scale required to meet project objectives

Criterion 4: Multi-stakeholder Community and Provider Support

Weight: [20 points]

• Indication of support from multiple independent stakeholders (e.g., health plans, hospital systems, medical/professional societies and other provider organizations, institutions of higher educations, federally recognized state primary care and rural

 $^{^1}_3$ ϕ NC will work with applicants to ensure there will be no overlapping geographic service areas

health association(s), quality improvement organization(s), or public health agencies).

 Applicant has no relationships with any vendor or vendors of HIT products or services that pose a real or perceived conflict of interest.

Preliminary Application Review and Selection Process

HHS staff will serve as the objective review panel to evaluate preliminary applications that meet the responsiveness and screening criteria to be eligible for further review.

Preliminary applications that are complete and responsive to the FOA administrative and content criteria (section III.1 and 2) will be evaluated for technical merit by an appropriate peer review group convened by HHS ONC and in accordance with HHS objective review using the review criteria stated above.

As part of the objective review, all applications will:

- be assessed and assigned a score; and
- receive a written critique.

The following will be considered in making decisions for requesting submission of a full application:

- merit of the proposed project as determined by objective review; and
- relevance of proposed project to program priorities.

Applicants will be notified by September 29, 2009, if they are requested to submit a full application for funding consideration. Those not selected to submit a full application will be notified by the same date. All notifications will be made to the email address used to submit the preliminary application.

Review Criteria for the Full Application

Pursuant to PHSA 3012(c)(7), as added by ARRA, the Secretary must consider the merits of the application, including those portions of the application regarding:

- geographical diversity and extent of service area;
- the types of service to be provided to health care providers;
- the ability of the applicant to provide assistance under this subsection and utilization of health information technology appropriate to the needs of particular categories of health care providers; and
- the percentage of funding and amount of in-kind commitment from other sources.

The following evaluation criteria will be used in the comprehensive evaluation of final applications. For each criterion, the weighting (out of a total of 100 points) is indicated to show the relative importance.

Criterion 1: Service Area Participation and Collaboration

Weight: [15 points]

- Number of primary-care providers in service area
- Synergy with other ONC-funded programs, including state-based health information exchange activities and forthcoming workforce training programs
- Potential for collaboration with other federal agencies and their grantees.

Criterion 2: Proposed Service Offerings

Weight: [30 points]

- Number of priority primary- care practices and providers in the service area that will be served
- Demonstrates an understanding of the meaningful use criteria and their evolution over time
- Demonstrates an understanding of the challenges in adoption and meaningful use of EHRs among small practices and other prioritized providers
- Proposes a feasible strategy for overcoming barriers to successful EHR adoption and meaningful use
- The proposed activities are clearly conceptualized and organized into components that interact harmoniously
- The proposal addresses all of the elements of the required scope for the types of service to be provided to health care providers

Criterion 3: Organizational Mission, Capability, and Experience

Weight: [20 points]

- Alignment of applicant's mission with the mission of the Extension Program
- The ability of the applicant to provide assistance, grounded in prior experience, under this subsection and utilization of health information technology appropriate to the needs of particular categories of health care providers
- The ability of the applicant's organizational and local resources, committed to the project upon award, to achieve the scale required to meet project objectives
- Applicant's past performance in related activities

Criterion 4: Multi-stakeholder Community and Provider Support

Weight: [30 points]

 Applicant's ability to become self-sustaining, based on review of Sustainability Plan

- Broad support from relevant stakeholders
- The percentage of funding and amount of in-kind commitment from other sources

Criterion 5: Reasonableness of the Budget

Weight: [5 points]

 Reasonableness of the proposed budget and its justification in context of the proposed geographic service area, service offerings, and technical approach.

Full Application Review and Selection Process

Applications that are complete and responsive to the FOA and that have been invited to respond to the full application review based on the outcome of the preliminary technical review will be evaluated for scientific and technical merit. HHS ONC will convene an objective review panel in accordance with HHS objective review procedures using the review criteria stated above.

As part of the objective review, all invited applications will:

- be independently reviewed and scored
- discussed with the panel and scored; and
- receive a written critique.

The following will be considered in making funding decisions:

- merit of the proposed project as determined by objective review;
- availability of funds; and
- relevance of the proposed project in relation to program priorities including geographic diversity and coverage of underserved areas.

VI. Award Administration Information

Preliminary Application Determinations

ONC will notify each applicant as to whether they will be invited to submit a full application after the review of the preliminary application. This notification will serve as the applicant's formal notice from ONC to apply for full application for the specified service area. Further guidance will be issued by ONC on the guidance for completing a full application and the notification of funding should an application be awarded.

Administrative and National Policy Requirements

The award is subject to HHS Administrative Requirements, which can be found in 45CFR Part 74 and 92 and the Standard Terms and Conditions implemented through the HHS Grants Policy Statement located at

http://www.hhs.gov/grantsnet/adminis/gpd/index.htm.

HHS Grants Policy Statement

ONC awards are subject to the requirements of the HHS Grants Policy Statement (HHS GPS) that are applicable to the grant/cooperative agreement based on recipient type and purpose of award. This includes, as applicable, any requirements in Parts I and II of the HHS GPS that apply to the award, as well as any requirements of Part IV. The HHS GPS is available at http://www.hhs.gov/grantsnet/adminis/gpd/. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the Notice of Award).

Records Retention

Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of three years from the date the final annual FSR is submitted and approved. For awards where the FSR is submitted at the end of the competitive segment, the three -year retention period will be calculated from the date the FSR for the entire competitive segment is submitted. Those recipients must retain the records pertinent to the entire competitive segment for three years from the date the FSR is submitted and approved. See 45 CFR 74.53 and 92.42 for exceptions and qualifications to the three-year retention requirement (e.g., if any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken). Those sections also specify the retention period for other types of grant-related records, including indirect cost proposals and property records. See 45 CFR 74.48 and 92.36 for record retention and access requirements for contracts under grants.

Reporting

The FSR is due quarterly and the ONC program progress report is due semi-annually. Final performance and FSRs are due 90 days of the end of each budget and project period.

Successful recipients will be required to submit progress and performance reports as outlined by ongoing program guidance, the Notice of Award, and as required to comply with all reporting requirements of ARRA.

Cooperative Agreement Terms and Conditions of Award

This section details the specific terms and conditions applicable to successful awarding of full applications, not preliminary applications. Upon award of a cooperative agreement, the following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when state and local Governments are eligible to apply), and other HHS, PHS, and ONC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, in which substantial ONC programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the ONC purpose is to support and stimulate the recipients' activities by involvement in

and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and the ONC as defined below. To facilitate appropriate involvement, during the period of this cooperative agreement, ONC and the recipient will be in contact monthly and more frequently when appropriate. Requests to modify or amend the cooperative agreement or the work plan may be made by ONC or the recipient at any time. Modifications and/or amendments to the cooperative agreement or work plan shall be effective upon the mutual agreement of both parties, except where ONC is authorized under the Terms and Conditions of award, 45 CFR Part 74 or 92, or other applicable regulation or statute to make unilateral amendments.

1. Cooperative Agreement Roles and Responsibilities

a) Office of the National Coordinator for Health Information Technology (ONC)

ONC will have substantial involvement in program awards as outlined below:

- Technical Assistance This includes, but is not limited to, federal guidance on a variety of issues related to program implementation.
- Collaboration To facilitate compliance with the terms of the cooperative agreement and to more effectively support recipients, ONC will actively coordinate with critical stakeholders, including recipients of ONC cooperative agreements under Section 3013 of the PHSA as amended by ARRA, as needed.
- Program Evaluation As required by Section 3012 of the PHSA as amended by ARRA, ONC will conduct a biennial evaluation of each Regional Center that receives financial assistance under this program by an evaluation panel appointed by the Secretary.
- Project Officers ONC will assign specific Project Officers to each cooperative agreement award to support and monitor recipients throughout the project period.
- Conference and Training Opportunities ONC will provide opportunities for training and/or networking, via the National Learning Consortium facilitated by the HITRC.
- Release of Funds Approval ONC Project Officers will be responsible for requesting authorization for the release of funds for their assigned projects.
- Monitoring ONC Project Officers will monitor, on a regular basis, progress of each recipient. This monitoring may be by phone, document review, on-site visit, other meeting and by other appropriate means, such as reviewing program progress reports and Financial Status Reports (SF269). This monitoring will be to determine compliance with programmatic and financial requirements.

b) Recipients

Recipients and assigned points of contact retain the primary responsibility and dominant

role for planning, directing and executing the proposed project as outlined in the terms and conditions of the Cooperative Agreement and with substantial ONC involvement. Responsibilities include:

- Requirements Recipients shall comply with all current and future requirements
 of this Funding Opportunity Announcement, future ONC program guidance, the
 terms and conditions of the Award Notice, and any other requirement specified
 and approved by the Secretary.
- Collaboration -- Recipients are required to collaborate with the critical stakeholders listed in this Funding Opportunity Announcement and the ONC team and ONC supported initiatives, including but not limited to, cooperative agreements under Section 3013 of the PHSA as added by ARRA.
- Reporting Recipients are required to comply with all reporting requirements
 outlined in this Funding Opportunity Announcement and the terms and conditions
 of the cooperative agreement to ensure the timely release of funds.
- Program Evaluation Recipients are required to cooperate with the ONC-directed biennial evaluation.

c) Dispute Resolution

Both ONC and the recipient are expected to work in a collegial fashion to minimize misunderstandings and disagreements. ONC will resolve disputes by using alternative dispute resolution (ADR) techniques. ADR often is effective in reducing the cost, delay, and contentiousness involved in appeals and other traditional ways of handling disputes. ONC will determine the specific technique to be employed on a case-by-case basis. ADR techniques include mediation, neutral evaluation, and other consensual methods. ONC will make final determinations pertaining to cooperative agreements based on the output of these resolution methods.

2. Other Terms

Cooperative agreements are for a period of up to four years.

Requests to modify or amend this cooperative agreement may be made at any time by ONC or the recipient, which shall be effective upon mutual agreement of both parties and if not agreed to will be subject to the dispute resolution practice below.

Recipients must comply with reporting requirements of the cooperative agreement.

Special conditions may be placed on cooperative agreements. These are binding on recipients.

3. American Recovery and Reinvestment Act of 2009

HHS Standard Terms and Conditions

HHS award recipients must comply with all terms and conditions outlined in their award, including policy terms and conditions contained in applicable HHS Grant Policy Statements, and requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, unless they conflict or are superseded by the following terms and conditions implementing the American Recovery and

Reinvestment Act of 2009 (ARRA) requirements below. In addition to the standard terms and conditions of award, recipients receiving funds under Division A of ARRA must abide by the terms and conditions set out below. The terms and conditions below concerning civil rights obligations and disclosure of fraud and misconduct are reminders rather than new requirements, but the other requirements are new and are specifically imposed for awards funded under ARRA. Recipients are responsible for contacting their HHS grant/program managers/project officers for any needed clarifications.

Awards issued under this Funding Opportunity Announcement are also subject to the requirements set forth in Section 3012 of the PHSA, as added ARRA.

a) Preference for Quick Start Activities

In using funds for this award for infrastructure investment, recipients shall give preference to activities that can be started and completed expeditiously, including a goal of using at least 50 percent of the funds for activities that can be initiated not later than 120 days after the date of the enactment of ARRA. Recipients shall also use funds in a manner that maximizes job creation and economic benefit. (ARRA Sec. 1602)

b) Limit on Funds

None of the funds appropriated or otherwise made available in ARRA may be used by any state or local government, or any private entity, for any casino or other gambling establishment, aquarium, zoo, golf course, or swimming pool. (ARRA Sec. 1604)

c) ARRA: One-Time Funding

Unless otherwise specified, ARRA funding to existent or new recipients should be considered one-time funding.

d) Civil Rights Obligations

In conducting activities under any cooperative agreement executed as recipients have civil rights obligations under federal law, as referenced in the HHS Grants Policy Statement. Recipients and sub-recipients of ARRA funds or other federal financial assistance must comply with Title VI of the Civil Rights Act of 1964 (prohibiting race, color, and national origin discrimination), Section 504 of the Rehabilitation Act of 1973 (prohibiting disability discrimination), Title IX of the Education Amendments of 1972 (prohibiting sex discrimination in education and training programs), and the Age Discrimination Act of 1975 (prohibiting age discrimination in the provision of services). For further information and technical assistance, please contact the HHS Office for Civil Rights at (202) 619-0403, OCRmail@hhs.gov, or http://www.hhs.gov/ocr/civilrights/.

e) Disclosure of Fraud or Misconduct

Each recipient or sub-recipient awarded funds made available under ARRA shall promptly refer to the HHS Office of Inspector General any credible evidence that a principal, employee, agent, contractor, sub-recipient, subcontractor, or other person has submitted a false claim under the False Claims Act or has committed a criminal or civil violation of laws pertaining to fraud, conflict of interest, bribery, gratuity, or similar misconduct involving those funds. The HHS Office of Inspector General can be reached at http://www.oig.hhs.gov/fraud/hotline/.

f) Responsibilities for Informing Sub-recipients

Recipients agree to separately identify to each sub-recipient, and document at the time of sub-award and at the time of disbursement of funds, the federal award number, any special CFDA number assigned for ARRA purposes, and amount of ARRA funds.

g) ARRA Transactions listed in Schedule of Expenditures of Federal Awards and Recipient Responsibilities for Informing Sub-recipients

- (a) To maximize the transparency and accountability of funds authorized under ARRA as required by Congress and in accordance with 45 CFR 74.21 and 92.20 "Uniform Administrative Requirements for Grants and Agreements", as applicable, and OMB A-102 Common Rules provisions, recipients agree to maintain records that identify adequately the source and application of ARRA funds.
- (b) For recipients covered by the Single Audit Act Amendments of 1996 and OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations," recipients agree to separately identify the expenditures for federal awards under ARRA on the Schedule of Expenditures of Federal Awards (SEFA) and the Data Collection Form (SF-SAC) required by OMB Circular A-133. This shall be accomplished by identifying expenditures for federal awards made under ARRA separately on the SEFA, and as separate rows under Item 9 of Part III on the SF-SAC by CFDA number, and inclusion of the prefix "ARRA-" in identifying the name of the federal program on the SEFA and as the first characters in Item 9d of Part III on the SF-SAC.
- (c) Recipients agree to separately identify to each sub recipient, and document at the time of sub-award and at the time of disbursement of funds, the federal award number, CFDA number, and amount of ARRA funds. When a recipient awards ARRA funds for an existing program, the information furnished to sub-recipients shall distinguish the sub-awards of incremental ARRA funds from regular sub-awards under the existing program.
- (d) Recipients agree to require their sub-recipients to include on their SEFA information to specifically identify ARRA funding similar to the requirements for the recipient SEFA described above. This information is needed to allow the recipient to properly monitor sub-recipient expenditure of ARRA funds as well as oversight by the federal awarding agencies, Offices of Inspector General and the Government Accountability Office.

h) Recipient Reporting

Reporting and Registration Requirements under Section 1512 of ARRA.

- (a) This award requires the recipient to complete projects or activities which are funded under ARRA and to report on use of ARRA funds provided through this award. Information from these reports will be made available to the public.
- (b) The reports are due no later than ten calendar days after each calendar quarter in which the recipient receives the assistance award funded in whole or in part by ARRA.
- (c) Recipients and their first-tier recipients must maintain current registrations in the Central Contractor Registration (www.ccr.gov) at all times during which they have active federal awards funded with ARRA funds. A Dun and Bradstreet Data Universal Numbering System (DUNS) Number (www.dnb.com) is one of the requirements for registration in the Central Contractor Registration.

- (d) The recipient shall report the information described in section 1512(c) using the reporting instructions and data elements that will be provided online at http://www.FederalReporting.gov and ensure that any information that is pre-filled is corrected or updated as needed.
- (e) Guidance for adhering to ARRA Reporting Requirements is addressed in an OMB Memorandum issued June 22, 2009:

<u>http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m09-21.pdf</u>. Applicants are required to adhere to all of these reporting requirements, as well as future requirements as issued by OMB.

4. Reporting

All reporting requirements will be provided to applicants of successful full applications, adherence to which is a required condition of any award. In general, the successful applicant under this guidance must comply with the following reporting and review activities:

a) Audit Requirements

The recipient shall comply with audit requirements of Office of Management and Budget (OMB) Circular A-133. Information on the scope, frequency, and other aspects of the audits can be found on the Internet at www.whitehouse.gov/omb/circulars;

b) Financial Status Reports

The recipient shall submit an annual Financial Status Report. An FSR is due no later than 90 days after the award end date and that failure to submit these timely could affect future funding. The report is an accounting of expenditures under the project that year. More specific information on this reporting requirement will be included in the Notice of Grant Award.

c) Progress Reports

Progress Reports will be evaluated by ONC and are required on a semi-annual basis. ONC will provide required additional reporting instructions after awards are made.

d) ARRA-Specific Reporting

Quarterly Financial and Programmatic Reporting: Consistent with ARRA emphasis on accountability and transparency, reporting requirements under ARRA programs will differ from and expand upon HHS's standard reporting requirements for grants. In particular, section 1512(c) of ARRA sets out detailed requirements for quarterly reports that must be submitted within 10 days of the end of each calendar quarter. Receipt of funds will be contingent on meeting ARRA reporting requirements.

The information from recipient reports will be posted on a public website. To the extent that funds are available to pay a recipient's administrative expenses, those funds may be used to assist the recipient in meeting the accelerated time-frame and extensive reporting requirements of ARRA.

Additional instructions and guidance regarding required reporting will be provided as they become available. For planning purposes, however, all applicants shall be aware that ARRA section 1512(c) provides as follows:

<u>Recipient Reports:</u> Not later than 10 days after the end of each calendar quarter, each recipient that received recovery funds from a federal agency shall submit a report to that agency that contains—

- (1) the total amount of recovery funds received from that agency;
- (2) the amount of recovery funds received that were expended or obligated to projects or activities; and
- (3) a detailed list of all projects or activities for which recovery funds were expended or obligated, including--
 - (A) the name of the project or activity;
 - (B) a description of the project or activity;
 - (C) an evaluation of the completion status of the project or activity;
 - (D) an estimate of the number of jobs created and the number of jobs retained by the project or activity; and
 - (E) for infrastructure investments made by state and local governments, the purpose, total cost, and rationale of the agency for funding the infrastructure investment with funds made under this Act, and name of the person to contact at the agency if there are concerns with the infrastructure investment.
- (4) Detailed information on any subcontracts or sub grants awarded by the recipient to include the data elements required to comply with the federal Funding Accountability and Transparency Act of 2006 (Public Law 109-282), allowing aggregate reporting on awards below \$25,000 or to individuals, as prescribed by the Director of the Office of Management and Budget. OMB guidance for implementing and reporting ARRA activities can be found at http://www.whitehouse.gov/omb/recovery_default/

To assist in fulfilling the accountability objectives of ARRA, as well as the Department's responsibilities under the Government Performance and Results Act of 1993 (GPRA), Public Law 103-62, applicants who receive funding under this program must provide data that measure the results of their work. Performance measures include the number of jobs

saved and jobs created due to ARRA Funding. Additionally, applicants must discuss their data collection methods in the application.

VII. Agency Contacts

Program Contact:

Health Information Technology Extension Program Implementation Team

Office of the National Coordinator for Health Information Technology

Email: regional-center-applications@hhs.gov

This funding announcement is subject to restrictions on oral conversations during the period of time commencing with the submission of a formal application² by an individual or entity and ending with the award of the competitive funds. Federal officials may not participate in oral communications initiated by any person or entity concerning a pending application for a Recovery Act competitive grant or other competitive form of Federal financial assistance, whether or not the initiating party is a federally registered lobbyist. This restriction applies unless:

- (i) the communication is purely logistical;
- (ii) the communication is made at a widely attended gathering;
- (iii) the communication is to or from a Federal agency official and another Federal Government employee;
- (iv) the communication is to or from a Federal agency official and an elected chief executive of a state, local or tribal government, or to or from a Federal agency official and the Presiding Officer or Majority Leader in each chamber of a state legislature; or
- (v) the communication is initiated by the Federal agency official.

² Formal Application includes the preliminary application and letter of intent phases of the program.

For additional information see http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m09-24.pdf .

VIII. Other Information

Additional information not previously mentioned within this Funding Opportunity Announcement is included in the Appendices in the following topic areas:

- Glossary (Appendix F)
- ARRA-Required Performance Measures (Appendix G)
- Survey Instructions on Ensuring Equal Opportunity for Applicants (Appendix H)
- Privacy and Security Resources (Appendix I)

IX. Appendices

- A. Statutory Text for Extension Program
- B. B.1 Health Information Technology Research Center (HITRC)
 - B.2 Priority Grants Programs Background
- C. Instructions for Completing the Budget Forms
- D. Suggested Format for Letter of Support from State Medicaid Director
- E. Conflict of Interest Certification Template
- F. Glossary
- G. ARRA-Required Performance Measures
- H. Survey Instructions on Ensuring Equal Opportunity for Applicants
- I. Privacy and Security Resources

Appendix A -- Statutory Text for Extension Program

The Health Information Technology Extension Program is authorized by Section 3012 of the PHSA, as added by ARRA. The full text of PHSA 3012 follows.

"SEC. 3012. HEALTH INFORMATION TECHNOLOGY IMPLEMENTATION ASSISTANCE.

- "(a) HEALTH INFORMATION TECHNOLOGY EXTENSION PROGRAM.— To assist health care providers to adopt, implement, and effectively use certified EHR technology that allows for the electronic exchange and use of health information, the Secretary, acting through the Office of the National Coordinator, shall establish a health information technology extension program to provide health information technology assistance services to be carried out through the Department of Health and Human Services. The National Coordinator shall consult with other Federal agencies with demonstrated experience and expertise in information technology services, such as the National Institute of Standards and Technology, in developing and implementing this program.
- "(b) HEALTH INFORMATION TECHNOLOGY RESEARCH CENTER.— "(1) IN GENERAL.—The Secretary shall create a Health Information Technology Research Center (in this section referred to as the 'Center') to provide technical assistance and develop or recognize best practices to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 3004.
 - "(2) INPUT.—The Center shall incorporate input from—
 - "(A) other Federal agencies with demonstrated experience and expertise in information technology services such as the National Institute of Standards and Technology;
 - "(B) users of health information technology, such as providers and their support and clerical staff and others involved in the care and care coordination of patients, from the health care and health information technology industry; and
 - "(C) others as appropriate.
 - "(3) PURPOSES.—The purposes of the Center are to—
 - "(A) provide a forum for the exchange of knowledge and experience;
 - "(B) accelerate the transfer of lessons learned from existing public and private sector initiatives, including those currently receiving Federal financial support;
 - "(C) assemble, analyze, and widely disseminate evidence and experience related to the adoption, implementation, and effective use of health information technology that allows for the electronic exchange and use of information including through the regional centers described in subsection (c);
 - "(D) provide technical assistance for the establishment and evaluation of regional and

local health information networks to facilitate the electronic exchange of information across health care settings and improve the quality of health care;

- "(E) provide technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information; and
- "(F) learn about effective strategies to adopt and utilize health information technology in medically underserved communities.

"(c) HEALTH INFORMATION TECHNOLOGY REGIONAL EXTENSION CENTERS.—

- "(1) IN GENERAL.—The Secretary shall provide assistance for the creation and support of regional centers (in this subsection referred to as 'regional centers') to provide technical assistance and disseminate best practices and other information learned from the Center to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 3004. Activities conducted under this subsection shall be consistent with the strategic plan developed by the National Coordinator, (and, as available) under section 3001.
- "(2) AFFILIATION.—Regional centers shall be affiliated with any United States-based nonprofit institution or organization, or group thereof, that applies and is awarded financial assistance under this section. Individual awards shall be decided on the basis of merit.
- "(3) OBJECTIVE.—The objective of the regional centers is to enhance and promote the adoption of health information technology through—
 - "(A) assistance with the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to healthcare providers nationwide;
 - "(B) broad participation of individuals from industry, universities, and State governments;
 - "(C) active dissemination of best practices and research on the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to health care providers in order to improve the quality of healthcare and protect the privacy and security of health information;
 - "(D) participation, to the extent practicable, in health information exchanges;
 - "(E) utilization, when appropriate, of the expertise and capability that exists in Federal agencies other than the Department; and
 - "(F) integration of health information technology, including electronic health records, into the initial and ongoing training of health professionals and others in the healthcare industry that would be instrumental to improving the quality of healthcare through the smooth and accurate electronic use and exchange of health information.
- "(4) REGIONAL ASSISTANCE.—Each regional center shall aim to provide assistance and education to all providers in a region, but shall prioritize any direct assistance first to the following:
 - "(A) Public or not-for-profit hospitals or critical access hospitals.
 - "(B) Federally qualified health centers (as defined in section 1861(aa)(4) of the Social Security Act).
 - "(C) Entities that are located in rural and other areas that serve uninsured, underinsured,

- and medically underserved individuals (regardless of whether such area is urban or rural).
- "(D) Individual or small group practices (or a consortium thereof) that are primarily focused on primary care.
- "(5) FINANCIAL SUPPORT.—The Secretary may provide financial support to any regional center created under this subsection for a period not to exceed four years. The Secretary may not provide more than 50 percent of the capital and annual operating and maintenance funds required to create and maintain such a center, except in an instance of national economic conditions which would render this cost-share requirement detrimental to the program and upon notification to Congress as to the justification to waive the cost-share requirement.
- "(6) NOTICE OF PROGRAM DESCRIPTION AND AVAILABILITY OF FUNDS.—The Secretary shall publish in the Federal Register, not later than 90 days after the date of the enactment of this title, a draft description of the program for establishing regional centers under this subsection. Such description shall include the following:
 - "(A) A detailed explanation of the program and the programs goals.
 - "(B) Procedures to be followed by the applicants.
 - "(C) Criteria for determining qualified applicants.
 - "(D) Maximum support levels expected to be available to centers under the program.
- "(7) APPLICATION REVIEW.—The Secretary shall subject each application under this subsection to merit review. In making a decision whether to approve such application and provide financial support, the Secretary shall consider at a minimum the merits of the application, including those portions of the application regarding—
 - "(A) the ability of the applicant to provide assistance under this subsection and utilization of health information technology appropriate to the needs of particular categories of health care providers;
 - "(B) the types of service to be provided to health care providers;
 - "(C) geographical diversity and extent of service area; and
 - "(D) the percentage of funding and amount of in-kind commitment from other sources.
- "(8) BIENNIAL EVALUATION.—Each regional center which receives financial assistance under this subsection shall be evaluated biennially by an evaluation panel appointed by the Secretary. Each evaluation panel shall be composed of private experts, none of whom shall be connected with the center involved, and of Federal officials. Each evaluation panel shall measure the involved center's performance against the objective specified in paragraph (3). The Secretary shall not continue to provide funding to a regional center unless its evaluation is overall positive.
- "(9) CONTINUING SUPPORT.—After the second year of assistance under this subsection, a regional center may receive additional support under this subsection if it has received positive evaluations and a finding by the Secretary that continuation of Federal funding to the center was in the best interest of provision of health information technology extension services."

Appendix B.1 - Health Information Technology Research Center (HITRC)

The HITRC will be established to provide technical assistance and develop or recognize best practices to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 3004 of the HITECH Act.

The HITRC will incorporate input from relevant sources, including:

- Other federal agencies with demonstrated experience and expertise in information technology services;
- Users of health information technology such as providers and their support and clerical staff and others involved in the care and care coordination of patients, from the health care and health information technology industry; and others as appropriate.

The purposes of the HITRC are to:

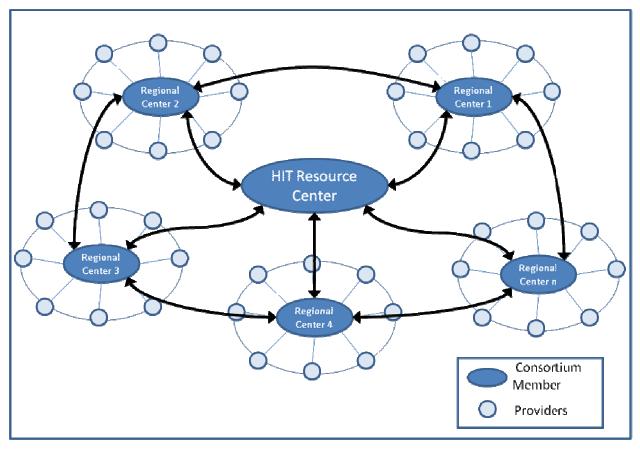
- Provide a forum for the exchange of knowledge and experience;
- Accelerate the transfer of lessons learned from existing public and private sector initiatives, including those currently receiving federal financial support;
- Assemble, analyze, and widely disseminate evidence and experience related to the
 adoption, implementation, and effective use of health information technology that
 allows for the electronic exchange and use of information including through the
 Regional Centers;
- Provide technical assistance for the establishment and evaluation of regional and local health information networks to facilitate the electronic exchange of information across health care settings and improve the quality of health care;
- Provide technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information; and
- Learn about effective strategies to adopt and utilize health information technology in medically underserved communities.

The HITRC and the Regional Centers together are referred to as the Extension Program and form the National Learning Consortium (see illustration below). Regional Centers will become part of the consortium upon award.

(Note: This Funding Opportunity Announcement is specific and limited to establishment of the Regional Centers. The HITRC will be established via contracting rather than cooperative agreement mechanisms. Proposals to furnish services as the HITRC are outside the scope of this funding opportunity announcement.)

The illustration below graphically represents the interaction among members of the consortium facilitated by HITRC and between Regional Centers and providers in relation to the Health Information Technology Extension Program.

Illustration of the National Learning Consortium



Appendix B.2 - Priority Grants Programs Background

On February 17, 2009, the President signed the American Recovery and Reinvestment Act of 2009 (ARRA). This statute includes The Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) that sets forth a plan for advancing the appropriate use of health information technology to improve quality of care and establish a foundation for health care reform. The Office of the National Coordinator for Health Information Technology (ONC) was statutorily established by the HITECH Act within the U.S. Department of Health and Human Services (HHS). ONC serves as the principal federal entity charged with coordinating the overall effort to implement a nationwide health information technology infrastructure that allows for the use and exchange of health information in electronic format.

The HITECH Act authorizes the Centers for Medicare & Medicaid Services (CMS) to administer incentives to eligible professionals (EPs) and hospitals for meaningful use of electronic health records (EHRs). It is anticipated these incentives will accelerate adoption of EHRs needed to reach the goal of all Americans having a secure EHR. To achieve the vision of a transformed health system that health information technology (HIT) can facilitate, there are three critical short-term prerequisites:

- Clinicians and hospitals must acquire and implement certified EHRs in a way that fully integrates these tools into the care delivery process;
- Technical, legal, and financial supports are needed to enable information to flow securely to wherever it is needed to support health care and population health; and,
- A skilled workforce needs to support the adoption of EHRs, information exchange across
 health care providers and public health authorities, and the redesign of work-flows within
 health care settings to gain the quality and efficiency benefits of EHRs, while maintaining
 individual privacy and security.

Priority Programs. The HITECH Act also authorizes the establishment of several new grant programs that will provide resources to address these prerequisites. Together, they are expected to facilitate the adoption and effective use of EHRs by providing technical assistance, the capacity to exchange health information, and the availability of trained professionals to support these activities. These priority grant programs are:

- Health Information Technology Extension Program (Extension Program), authorized by PHSA Section 3012, as added by ARRA will establish a collaborative consortium of Health Information Technology Regional Extension Centers (Regional Centers) facilitated by the national Health Information Technology Research Center (HITRC). The Extension Program will offer providers across the nation technical assistance in the selection, acquisition, implementation, and meaningful use of an EHR to improve health care quality and outcomes. (The Extension Program's Regional Centers are the topic of this Funding Opportunity Announcement.)
- State Grants to Promote Health Information Technology (State Health Information Exchange Cooperative Agreements Program), authorized by PHSA Section 3013, as added by ARRA to promote health information exchange (HIE) that will advance mechanisms for information sharing across the health care system.
- <u>Information Technology Professionals in Health Care (Workforce Program)</u>, authorized by PHSA Section 3016, as added by ARRA to fund the training and development of a

workforce that will meet short-term HITECH Act programmatic needs.

Appendix C - Instructions for Completing the Required Budget Forms

This section provides step-by-step instructions for completing the four (4) standard Federal forms required as part of your grant application, including special instructions for completing Standard Budget Forms 424 and 424A. Standard Forms 424 and 424A are used for a wide variety of Federal grant programs, and Federal agencies have the discretion to require some or all of the information on these forms. Accordingly, please use the instructions below in lieu of the standard instructions attached to SF 424 and 424A to complete these forms.

a. Standard Form 424

- **1. Type of Submission:** (Required): Select one type of submission in accordance with agency instructions.
- Preliminary Application Application Changed/Corrected Application If requested, check if this submission is to change or correct a previously submitted application.
- **2. Type of Application:** (Required) Select one type of application in accordance with agency instructions.
- New. Continuation Revision
- **3. Date Received:** Leave this field blank.
- **4. Applicant Identifier:** Leave this field blank

5a Federal Entity Identifier: Leave this field blank

- **5b. Federal Award Identifier:** For new applications leave blank. For a continuation or revision to an existing award, enter the previously assigned Federal award (grant) number.
- **6. Date Received by State:** Leave this field blank.
- **7. State Application Identifier:** Leave this field blank.

- **8. Applicant Information:** Enter the following in accordance with agency instructions:
- **a. Legal Name:** (Required): Enter the name that the organization has registered with the Central Contractor Registry. Information on registering with CCR may be obtained by visiting the grants.gov website.
- **b.** Employer/Taxpayer Number (EIN/TIN): (Required): Enter the Employer or Taxpayer Identification Number (EIN or TIN) as assigned by the Internal Revenue Service.
- **c. Organizational DUNS:** (Required) Enter the organization's DUNS or DUNS+4 number received from Dun and Bradstreet. Information on obtaining a DUNS number may be obtained by visiting the grants.gov website.
- **d. Address:** (Required) Enter the complete address including the county.
- **e. Organizational Unit:** Enter the name of the primary organizational unit (and department or division, if applicable) that will undertake the project.
- **f. Name and contact information of person to be contacted on matters involving this application:** Enter the name (First and last name required), organizational affiliation (if affiliated with an organization other than the applicant organization), telephone number (Required), fax number, and email address (Required) of the person to contact on matters related to this application.
- **9. Type of Applicant:** (Required) Select the applicant organization "type" from the following drop down list.

A. State Government B. County Government C. City or Township Government D. Special District Government E. Regional Organization F. U.S. Territory or Possession G. Independent School District H. Public/State Controlled Institution of Higher Education I. Indian/Native American Tribal Government (Federally Recognized) J. Indian/Native American Tribal Government (Other than Federally Recognized) K. Indian/Native American Tribally Designated Organization L. Public/Indian Housing Authority M. Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education) N. Nonprofit without 501C3 IRS Status (Other than Institution of Higher Education) O. Private Institution of Higher Education P. Individual Q. For-Profit Organization (Other than Small Business) R. Small Business S. Hispanic-serving Institution T. Historically Black Colleges and Universities (HBCUs) U. Tribally Controlled Colleges and Universities (TCCUs) V. Alaska Native and Native Hawaiian Serving Institutions W. Non-domestic (non-US) Entity X. Other (specify)

10. Name Of Federal Agency: (Required) Enter U.S. Assistant Secretary for Preparedness and

- **11. Catalog Of Federal Domestic Assistance Number/Title:** The CFDA number can be found on page one of the Program Announcement.
- **12. Funding Opportunity Number/Title:** (Required) The Funding Opportunity Number and title of the opportunity can be found on page one of the Program Announcement.
- 13. Competition Identification Number/Title: Leave this field blank.
- **14. Areas Affected By Project:** List the largest political entity affected (cities, counties, state, etc).
- **15. Descriptive Title of Applicant's Project:** (Required) Enter a brief descriptive title of the project.
- **16.** Congressional Districts Of: (Required) 16a. Enter the applicant's Congressional District, and 16b. Enter all district(s) affected by the program or project. Enter in the format: 2 characters State Abbreviation 3 characters District Number, e.g., CA-005 for California 5th district, CA-012 for California 12th district, NC-103 for North Carolina's 103rd district. If all congressional districts in a state are affected, enter "all" for the district number, e.g., MD-all for all congressional districts in Maryland. If nationwide, i.e. all districts within all states are affected, enter US-all.
- **17. Proposed Project Start and End Dates:** (Required) Enter the proposed start date and final end date of the project. Therefore, if you are applying for a multi-year grant, such as a 2 year grant project, the final project end date will be 2 years after the proposed start date.
- **18. Estimated Funding:** (Required) Enter the amount requested or to be contributed during each funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines, as applicable. If the action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses.

NOTE: Applicants should review cost sharing principles contained in Subpart C of 45 CFR Part 74 or 45 CFR Part 92 before completing Item 18 and the Budget Information Sections A, B and C noted below.

All budget information entered under item 18 should cover the upcoming 2-year budget period. For sub-item 18a, enter the Federal funds being requested. Sub-items 18b-18e are considered 54

funds creditable toward awardee cost share requirement. The dollar amounts entered in subitems 18b-18f must total at least 1/3rd of the amount of Federal funds being requested (the amount in 18a). For a full explanation of ONC's cost sharing requirements, see the information in the box below. For sub-item 18f, enter only the amount, if any, which is going to be used as part of the required cost share.

There are two types of resource that can be considered to contribute to awardee cost share requirement: 1) non-Federal cash and 2) non-Federal in-kind. In general, costs borne by the applicant and cash contributions of any and all third parties involved in the project, including sub-grantees, contractors and consultants, are considered funds creditable toward cost share proportion. Generally, most contributions from sub-contractors or sub-grantees (third parties) will be non-Federal in-kind funds. Volunteered time and use of facilities to hold meetings or conduct project activities may be considered in-kind (third party) donations. Examples of non-Federal cash resources includes budgetary funds provided from the applicant agency's budget for costs associated with the project.

NOTE: Indirect charges may only be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another Federal agency; or (2) the applicant is a state or local government agency. State governments should enter the amount of indirect costs determined in accordance with HHS requirements. If indirect costs are to be included in the application, a copy of the approved indirect cost agreement must be included with the application. Further, if any sub-contractors or sub-grantees are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.

ONC's Cost Sharing Requirement

Under this program, ONC's cost share requirement is \$1 for every \$9 Federal dollars for the first and second years of the program. In other words, for every nine dollars received in Federal funding, the applicant must contribute at least one (1) dollar in non-Federal resources toward the project's total annual cost. In the third and fourth years of the program, ONC's cost share requirement is \$9 for every \$1 Federal dollars of the program. In other words, for every one dollar received in Federal funding, the applicant must contribute at least nine dollars in non-Federal resources toward the project's total annual cost. This ratio is reflected in the following formulas which you can use to calculate your minimum required cost share:

Years One and Two:

Minimum

Federal Funds Requested = Cost Share

9

Requirement

For example, if you request \$9,000,000 in Federal funds, then your minimum cost share requirement is \$9,000,000/9 or \$1,000,000. In this example the **project's total annual cost** would be at least \$10,000,000.

Years Three and Four:

Minimum

Federal Funds Requested X 9 = Cost Share

Requirement

For example, if you request \$300,000 in Federal funds, then your <u>minimum</u> cost share requirement is \$300,000 X 9 or \$2,700,000. In this example the **project's total annual cost** would be at least \$3,000,000.

If the required non-Federal share is not met by a funded project, ONC will disallow any Federal dollars that do not meet the required threshold.

Examples of revenue sources that recipient should consider to help them meet the cost sharing requirements include: charging providers for direct technical assistance, and accepting assignment of the Medicaid EHR incentive payments to support eligible Medicaid providers achieve EHR meaningful use, Section 1903(t)(1) of the Social Security Act, as added by ARRA.

- **19. Is Application Subject to Review by State Under Executive Order 12372 Process?** Check c. Program is not covered by E.O. 12372
- **20. Is the Applicant Delinquent on any Federal Debt?** (Required) This question applies to the applicant organization, not the person who signs as the authorized representative. If yes, include an explanation on the continuation sheet.
- **21. Authorized Representative:** (Required) To be signed and dated by the authorized representative of the applicant organization. Enter the name (First and last name required) title (Required), telephone number (Required), fax number, and email address (Required) of the person authorized to sign for the applicant. A copy of the governing body's authorization for you to sign this application as the official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

b. Standard Form 424A

NOTE: Standard Form 424A is designed to accommodate applications for multiple grant programs; thus, for purposes of this program, many of the budget item columns and rows are not applicable. You should only consider and respond to the budget items for which guidance is provided below. Unless otherwise indicated, the SF 424A should reflect a one year budget.

Section A - Budget Summary

<u>Line 5:</u> Leave columns (c) and (d) blank. Enter TOTAL Federal costs in column (e) and total non-Federal costs (including third party in-kind contributions and any program income to be used as part of the grantee cost share contribution) in column (f). Enter the sum of columns (e) and (f) in column (g).

Section B - Budget Categories

Column 3: Enter the breakdown of how you plan to use the Federal funds being requested by object class category (see instructions for each object class category below).

Column 4: Enter the breakdown of how you plan to use the non-Federal share by object class category.

Column 5: Enter the total funds required for the project (sum of Columns 3 and 4) by object class category.

Separate Budget Detail Requirement

1. You must submit a separate Budget Narrative/Justification as part of your application. Please see <u>Budget Detail</u>, <u>Page 1 – Sample Format with EXAMPLES for more detail</u>.

For your use in developing and presenting your Budget Narrative/Justification, a sample format with examples and a blank sample template have been included in these Attachments. In your Budget Narrative/Justification, you should include a breakdown of the budgetary costs for all of the object class categories noted in Section B, across three columns: Federal; non-Federal cash; and non-Federal in-kind. Cost breakdowns, or justifications, are required for any cost of \$1,000 or more. The Budget Narratives/Justifications should fully explain and justify the costs in each of the major budget items for each of the object class categories, as described below. Non-Federal cash as well as, sub-contractor or sub-grantee (third party) in-kind contributions designated as contributing to the cost share proportion must be clearly identified and explained in the Budget Narrative/Justification. The full Budget Narrative/Justification should be included in the application immediately following the SF 424 forms.

<u>Line 6a: Personnel:</u> Enter total costs of salaries and wages of applicant/grantee staff. Do not include the costs of consultants; consultant costs should be included under 6h - Other. In the Budget Narrative/Justification: Identify the project director, if known. Specify the key staff, their titles, brief summary of project related duties, and the percent of their time commitments to the project in the Budget Narrative/Justification.

<u>Line 6b:</u> <u>Fringe Benefits:</u> Enter the total costs of fringe benefits unless treated as part of an approved indirect cost rate. In the Justification: Provide a break-down of amounts and percentages that comprise fringe benefit costs, such as health insurance, FICA, retirement insurance, etc.

<u>Line 6c:</u> <u>Travel:</u> Enter total costs of out-of-town travel (travel requiring per diem) for staff of the project. Do not enter costs for consultant's travel - this should be included in line 6h. In the Justification: Include the total number of trips, destinations, purpose, length of stay, subsistence

allowances and transportation costs (including mileage rates).

<u>Line 6d: Equipment:</u> Enter the total costs of all equipment to be acquired by the project. For all grantees, "equipment" is non-expendable tangible personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit. If the item does not meet the \$5,000 threshold, include it in your budget under Supplies, line 6e. In the Justification: Equipment to be purchased with Federal funds must be justified as necessary for the conduct of the project. The equipment must be used for project-related functions; the equipment, or a reasonable facsimile, must not be otherwise available to the applicant or its sub-grantees. The justification also must contain plans for the use or disposal of the equipment after the project ends.

<u>Line 6e: Supplies:</u> Enter the total costs of all tangible expendable personal property (supplies) other than those included on line 6d. In the Justification: Provide general description of types of items included.

Line 6f: Contractual: Enter the total costs of all contracts, including (1) procurement contracts (except those, which belong on other lines such as equipment, supplies, etc.). Also include any contracts with organizations for the provision of technical assistance. Do not include payments to individuals or consultants on this line. In the Budget Narrative/Justification: Attach a list of contractors indicating the name of the organization, the purpose of the contract, and the estimated dollar amount. If the name of the contractor, scope of work, and estimated costs are not available or have not been negotiated, indicate when this information will be available. Whenever the applicant/grantee intends to delegate more than 33% of a project's total budget to the contractual line item, the applicant/grantee must provide a completed copy of Section B of the SF 424A Budget Categories for each sub-contractor or sub-grantee, and separate Budget Narrative/Justification for each sub-contractor or sub-grantee for each year of potential grant funding.

<u>Line 6g: Construction:</u> Leave blank since construction is not an allowable cost under this program.

<u>Line 6h: Other:</u> Enter the total of all other costs. Such costs, where applicable, may include, but are not limited to: insurance, medical and dental costs (i.e. for project volunteers this is different from personnel fringe benefits); non-contractual fees and travel paid directly to individual consultants; local transportation (all travel which does not require per diem is considered local travel); postage; space and equipment rentals/lease; printing and publication; computer use; training and staff development costs (i.e. registration fees). If a cost does not clearly fit under another category, and it qualifies as an allowable cost, then rest assured this is where it belongs. In the Justification: Provide a reasonable explanation for items in this category. For individual consultants, explain the nature of services provided and the relation to

activities in the work plan. Describe the types of activities for staff development costs.

Line 6i: Total Direct Charges: Show the totals of Lines 6a through 6h.

<u>Line 6j:</u> <u>Indirect Charges:</u> Enter the total amount of indirect charges (costs), if any. If no indirect costs are requested, enter "none." Indirect charges may be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another Federal agency; or (2) the applicant is a state or local government agency.

Budget Narrative/Justification: <u>State governments should enter the amount of indirect costs</u> <u>determined in accordance with HHS requirements.</u> An applicant that will charge indirect costs to the grant **must enclose a copy of the current indirect cost rate agreement.** If any subcontractors or sub-grantees are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.

If the applicant organization is in the process of initially developing or renegotiating a rate, it should immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the cognizant agency's guidelines for establishing indirect cost rates, and submit it to the cognizant agency. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. It should be noted that when an indirect cost rate is requested, those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

Line 6k: Total: Enter the total amounts of Lines 6i and 6j.

<u>Line 7: Program Income:</u> As appropriate, include the estimated amount of income, if any, you expect to be generated from this project. Program Income must be used as additional program costs and cannot be credited as a non-Federal resource.

Section C - Non-Federal Resources

<u>Line 12:</u> Enter the amounts of non-Federal resources that will be used in carrying out the proposed project, by source (Applicant; State; Other) and enter the total amount in Column (e). Keep in mind that if the cost share requirement is not met, Federal dollars may be reduced.

Section D - Forecasted Cash Needs - Not applicable.

Section E - Budget Estimate of Federal Funds Needed for Balance of the Project

<u>Line 20:</u> Section E is relevant for multi-year grant applications, where the project period is 24 months or longer. This section does not apply to grant awards where the project period is less than 17 months.

Section F - Other Budget Information

<u>Line 22: Indirect Charges:</u> Enter the type of indirect rate (provisional, predetermined, final or fixed) to be in effect during the funding period, the base to which the rate is applied, and the total indirect costs. Include a copy of your current Indirect Cost Rate Agreement.

<u>Line 23: Remarks:</u> Provide any other comments deemed necessary.

c. Standard Form 424B - Assurances

This form contains assurances required of applicants under the discretionary funds programs administered by the Assistant Secretary for Preparedness and Response. Please note that a duly authorized representative of the applicant organization must certify that the organization is in compliance with these assurances.

d. Certification Regarding Lobbying

This form contains certifications that are required of the applicant organization regarding lobbying. Please note that a duly authorized representative of the applicant organization must attest to the applicant's compliance with these certifications.

e. Other Application Components

Survey on Ensuring Equal Opportunity for Applicants

The Office of Management and Budget (OMB) has approved an HHS form to collect information on the number of faith-based groups applying for a HHS grant. Non-profit organizations, excluding private universities, are asked to include a completed survey with their grant application packet. Attached you will find the OMB approved HHS "Survey on Ensuring Equal Opportunity for Applicants" form (Attachment F). Your help in this data collection process is greatly appreciated.

Proof of Non-Profit Status

Non-profit applicants must submit proof of non-profit status. Any of the following constitutes acceptable proof of such status:

- o A copy of a currently valid IRS tax exemption certificate.
- A statement from a state taxing body, state attorney general, or other appropriate state official
 certifying that the applicant organization has a non-profit status and that none of the net earnings
 accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

Indirect Cost Agreement

Applicants that have included indirect costs in their budgets must include a copy of the current indirect cost rate agreement approved by the Department of Health and Human Services or another Federal agency. This is optional for applicants that have not included indirect costs in their budgets.

2. Budget Detail, Page 1 - Sample Format with EXAMPLES

These are sample costs as to how they should be reflected in the template, and are suggested to offer guidelines when applicants are completing their budget justifications. Justifications must include supporting detail and narrative justification for the costs proposed. Sufficient detail should be provided to demonstrate costs as they pertain to the administration of the project. In any case, the applicant should assure that the narrative and justification are legible and clearly provide all required information.

INSTRUCTIONS:

The Budget Detail must include the following information:

An itemized breakout of proposed costs and sub-total of these costs for each Object Class Category listed in the template below.

A breakout of proposed costs by whether they are funded through Federal, Non-Federal Cash or Non-Federal In-Kind support.

A brief description of the expense or service in the Supporting Detail column, as they demonstrate costs pertaining to the administration of the project.

The time period in which the cost will be utilized in the Supporting Detail column.

Any pertinent information that will aid the reviewer in evaluating the proposed cost.

The Budget Detail must be supported by a narrative justification of why the proposed costs are necessary and reasonable to fulfill the purpose and achieve the milestones of the proposed project, in context of the proposed technical approach. An example of such justification would be:

Project Administrator Salary Costs – assumes at least a master's in public health or health administration, or equivalent degree, with at least 6 years' experience managing health services, programs, or providers. Salary is typical for this level of qualifications and responsibility in the proposed service area. Assumes this position would provide executive-level direction and management oversight.

Object Class Category	Federal Funds	Non- Federal Cash	Non- Federal In- Kind	TOTAL	Supporting Detail
Personnel	\$40,000	\$5,000		\$45,000	Project Administrator (name) = .3FTE @ \$50,000/yr = \$15,000 (\$10,000 = federal; \$5,000 = Non-federal cash) Project Director (name) = 1FTE @ \$30,000 = \$30,000 (federal)
Fringe Benefits	\$12,600	0	0	\$12,600	Fringes on Project Staff @ 28% of salary. (federal) FICA (7.65%) = \$ 3,442 Health (12%) = \$ 5,400 Dental (5%) = \$ 2,250 Life (2%) = \$ 900 Workers Comp Insurance (.75%) = \$ 338 Unemployment Insurance (.6%) = \$ 270

					Travel to 2 Annual Grantee Meetings: (federal)
					Airfare: 1 RT x 2 people x \$750/RT x 2 = \$3,000
					Lodging: 2 nights x 2 people x \$100/night x 2 = \$800
					Per Diem: 2 days x 2 people x \$40/day x 2 = \$ 320
					TOTAL: \$4,120
Travel	\$4,120	\$1,547		\$5,667	Out-of-Town Project Site Visits (Non-federal cash)
Travel					Car mileage:
					3 trips x 2 people x 350 miles/trip x \$.365/mile = \$ 767
					3 trips x 2 people x 1 night/trip x \$50/night = \$ 300
					3 trips x 2 people x 2 days/trip x \$40/day = \$ 480
					TOTAL: \$1,547
Equipment	0	0	0	0	No equipment requested
					Laptop computer for use in client intakes = \$1,340 (federal)
					Consumable supplies (paper, pens, etc.)
Supplies	\$1,340	\$2,160		\$3,500	\$100/mo x 12 months = \$1,200 (Non-federal cash)
					Copying \$80/mo x 12 months = \$ 960 (Non-federal cash)
					TOTAL: \$3,500

TOTAL	\$209,310	\$10,707	\$50,000	\$270,017	(Non-federal cash) TOTAL: \$4,200
Other	\$1,250	\$2,000		\$3,250	Printing brochures (25,000 @ \$0.05 ea) = \$ 1,250 (federal) Postage: \$150/mo x 12 months = \$ 1,800
					Local conf registration fee (provide conference name) = \$ 200 (Non-federal cash)
					TOTAL: \$200,000
					contractor C = \$50,000 (Non- federal in-kind)
Contractual	\$150,000		\$50,000	\$200,000	contractor B = \$75,000 (federal)
					contractor A = \$75,000 (federal)
					Contracts to A,B,C direct service providers (name providers)

3. <u>Budget Detail -- Sample Template</u>

Object Class Category	Federal Funds	Non- Federal Cash	Non- Federal In-Kind	TOTAL	Supporting Detail
Personnel					
Fringe Benefits					
Travel					
Equipme nt					
Supplies					
Contractu al					
Other					
Indirect Charges					
TOTAL					

Suggested Format for Letter from State Medicaid Director

Dear Mr./Ms. XX,

(Name of organization/group submitting the letter) is very interested in addressing (insert the issue being addressed by the grant application.) and (state why the issue is of concern.)

(State knowledge of proposal, knowledge of agency submitting proposal, and encouragement of funding entity to provide resources to address issue identified above.)

(State that applicant has been designated as an adoption entity for the entire state.)

(Conclude with general statement of confidence in and support for the organization seeking assistance, based on past experience with the applicant entity, reputation for effectiveness, etc.)

(Provide the following information for the point of contact in the supporting organization.)

Name

Title

Agency

Division (if applicable)

State

Address

Phone

Fax Number

Email

Appendix D - Conflict of Interest Certification Template

CONFLICT OF INTEREST CERTIFICATION

American Recovery and Reinvestment Act of 2009: Health Information Technology Extension Program: Regional Centers

DHHS Office:

CFDA Number:

FOA Number:

Legal Applicant Name:

Legal Vendor Name:

My signature below certifies that, in submitting the preliminary application for the above referenced award, there are no potential, real or perceived conflicts of interest relative to the anticipated collaboration between our organization _______ and the HIT vendor ______.

I also acknowledge my responsibility to disclose any future potential, real or perceived conflicts of interest, between our organization ______ with the HIT vendor ______ should the attestation within this certification change in the

future.

Organization Authorized Representative	Vendor Authorized Representative
Position of Authorized Representative	Position of Authorized Representative
Date	Date

Appendix E - Glossary

General Terms

EHR: For purposes of this Funding Opportunity Announcement, "electronic health record", "certified EHR" and "certified EHR technology" have been used interchangeably to signify electronic health record certified pursuant to Section 3001(c)(5) of the Public Health Service Act as added by the ARRA.

Qualified Electronic Health Record: As defined in Section 3000(13) of the Public Health Service Act as amended by ARRA, 'qualified electronic health record' means an electronic record of health-related information on an individual that:

(A) includes patient demographic and clinical health information, such as medical history and

problem lists; and

- (B) has the capacity:
 - (i) to provide clinical decision support;
 - (ii) to support physician order entry;
 - (iii) to capture and query information relevant to health care quality; and
 - (iv) to exchange electronic health information with, and integrate such information from other sources.

Health Information Exchange (HIE): For purposes of this Funding Opportunity Announcement, "Health Information Technology" or "HIE" is used to mean the electronic movement of health-related information among organizations according to nationally recognized standards.

Meaningful Use: Pursuant to Titles 18 and 19 of the Social Security Act as amended by Title IV in Division B of ARRA, the Secretary will propose and finalize a definition for meaningful EHR use through formal notice-and-comment rulemaking by the end of FY 2010.

For purposes of the Medicare incentive payments for meaningful use of certified EHR technology by eligible professionals (per Section 1848(o)(5) of the Social Security Act as added by Recovery Act, a physician, as defined in Social Security Act 1861(r)) and hospitals (Social Security Act 1886(d) hospitals and Critical Access Hospitals per Social Security Act 1814) provider shall be treated as meaningful users of certified EHR technology with respect to a payment year (or for an EHR reporting period with respect to that payment year) if the provider meets each of the requirements specified in the following table.

Eligible Professional Meaningful Use	Eligible Hospital Meaningful Use
Requirements per Social Security Act	Requirements per Social Security Act
1848(o)(2)	1886(n)(3)
(i) MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY. – The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the professional is using the certified EHR technology in a meaningful manner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary.	(i) MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY. – The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the professional is using the certified EHR technology in a meaningful manner.

Eligible Professional Meaningful Use Requirements per Social Security Act 1848(o)(2)	Eligible Hospital Meaningful Use Requirements per Social Security Act 1886(n)(3)
(ii) INFORMATION EXCHANGE. – The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.	(ii) INFORMATION EXCHANGE. – The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.
(iii) REPORTING ON MEASURES USING EHR. –Subject to subparagraph (B)(ii) and using such certified HER technology, the eligible professional submits information for such period, in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary under subparagraph (B)(i).	(iii) REPORTING ON MEASURES USING EHR. –Subject to subparagraph (B)(ii) and using such certified EHR technology, the eligible professional submits information for such period, in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary under subparagraph (B)(i).

Both Social Security Act Sections 1848(o) and 1886(n), as added by ARRA, require the Secretary to define more stringent meaningful use criteria over time. In 2015, eligible providers failing to demonstrate meaningful use pursuant to criteria defined by the Secretary, will be subject to financial penalties under Medicare Sections 4101(b) and 4102(b) of ARRA.

For access to the most current publicly available information on meaningful use, please visit the ONC programmatic website at: http://healthit.hhs.gov

Provider Terms

Primary-Care Physician: For purposes of this Funding Opportunity Announcement, "Primary-Care Physician" is defined as a licensed doctor of medicine or osteopathy practicing family practice, obstetrics and gynecology, general internal or pediatric medicine regardless of whether the physician is board certified in any of these specialties.

Individual primary-care physician practice: For purposes of this Funding Opportunity Announcement, "individual primary-care physician practice" is defined as a practice in which only one primary-care physician furnishes professional services. The practice may include one or more nurse practitioners and/or physician assistants in lieu of or in addition to registered and licensed vocational nurses, medical assistants, and office administrative staff.

Small-group primary-care physician practice: For purposes of this Funding Opportunity Announcement, "small-group primary-care physician practice" is defined as a group practice site that includes ten or fewer licensed doctors of medicine or osteopathy routinely furnish professional services, and where the majority of physicians practicing at least 2 days per week at the site practice family, general internal, or pediatric medicine. The practice may include nurse practitioners and/or physician assistants (regardless of their practice specialties) in addition to registered and licensed vocational nurses, medical assistants, and office administrative staff.

Note: a practice otherwise meeting the definition of individual or small-group physician practice, above, may participate in shared-services and/or group purchasing agreements, and/or reciprocal agreements for patient coverage, with other physician practices without affecting their status as individual or small-group practices for purposes of the Regional Centers.

Selected Definitions Relevant to the Medicare EHR Incentives

1886 (d) **Hospitals:** Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. This payment system is referred to as the inpatient prospective payment system (IPPS). Acute-care hospitals subject to IPPS 1886(d) are often referred to as 1886(d) hospitals.

Eligible Hospital: Per Title 18 of the Social Security Act as amended by Title IV in Division B of ARRA, an 1886(d) inpatient acute care hospital paid under the Medicare inpatient prospective payment system (IPPS) or an 1814(l) Critical Access Hospital (CAHs).

Non-eligible Hospital: Per Title 18 of the Social Security Act as amended by Title IV in Division B of ARRA, any hospital *other than* an acute-care hospital under 1886(d) or Critical Access Hospital under 1814(l). (Per SSA 1886(d), examples include Long-term Care Hospitals, Inpatient Rehabilitation Hospitals, Inpatient Psychiatric Hospitals, non-IPPS Cancer Centers and Children's Hospitals.)

Eligible Professional: For purposes of the Medicare incentive, an eligible professional is defined in Social Security Act Section 1848(o), as added by ARRA, as a physician as defined in Social Security Act 1861(r). The definition at 1861(r) includes doctors of medicine, doctors of osteopathy, doctors of dental surgery or of dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors.

Hospital-Based Professional: Social Security Act 1848(o)(1)(C)(ii), as added by ARRA, defines a 'hospital-based professional' for purposes of clause (i) of Social Security Act 1848(o)(1)(C). A hospital-based professional is an otherwise eligible professional, such as a pathologist, anesthesiologist, or emergency physician, who furnishes substantially all of his or her covered professional services in a hospital setting (whether inpatient or outpatient) and through the use of

the facilities and equipment, including qualified electronic health records, of the hospital. The determination of whether an eligible professional is a hospital-based eligible physician shall be made on the basis of the site of service (as defined by the Secretary) and without regard to any employment or billing arrangement between the priority primary-care provider and any other provider. Social Security Act 1848(o)(1)(C)(i) that no Medicare incentive payments for meaningful use of certified EHR technology may be made to hospital-based eligible professionals.

Selected Definitions Relevant to Medicaid EHR Incentives

Eligible professional: Social Security Act 1903(t)(3)(B), as added by ARRA, defines an eligible professional for Medicaid health IT incentives as a physician, dentist, certified nurse mid-wife, nurse practitioner, or a physician assistant practicing in a rural health clinic or FQHC that is led by a physician assistant, if he/she meets the criteria set forth in Social Security Act 1903(t)(2)(A) as added by ARRA.

Rural Health Clinic: For purposes of this Funding Opportunity Announcement, "rural health clinic" is defined as clinic providing primarily outpatient care certified to receive special Medicare and Medicaid reimbursement. RHCs provide increased access to primary care in underserved rural areas using both physicians and other clinical professionals such as nurse practitioners, physician assistants, and certified nurse midwives to provide services. For the statutory definition of a Rural Health Clinic for purposes of provider reimbursement, please see Section 1861(aa) of the Social Security Act.

Federally Qualified Health Center (FQHC): FQHCs are safety net providers such as community health centers, public housing centers, outpatient health programs funded by the Indian Health Service, and programs serving migrants and the homeless. For the statutory definition of an FQHC, please see Section 1861(aa) of the Social Security Act. For further information about FQHCs, please see either or both of the following resources:

- (1) the CMS Federally Qualified Health Center Fact Sheet, available online at http://www.cms.hhs.gov/MLNProducts/downloads/fqhcfactsheet.pdf; and/or
- (2) HRSA *Policy Information Notice 2003-21: Federally Qualified Health Center Look-Alike Guidelines and Application*, available online at http://bphc.hrsa.gov/policy/pin0321.htm

Eligible Hospital: The definition of Medicaid providers for purposes of eligibility for Medicaid HIT incentive payments, provided at Social Security Act 1903(t)(2)(B), as added by ARRA, is a Children's Hospital or an Acute Care Hospital with at least 10 percent patient volume attributable to Medicaid.

Other Definitions for the purpose of this announcement

<u>Note: Unless otherwise noted in the specific definition, the below terms are defined as used in this Funding Opportunity Announcement, for purposes of this announcement.</u>

Health IT: certified EHRs and other technology and connectivity required to meaningfully use and exchange electronic health information

Priority primary care providers: Primary-care providers in individual and small group practices (fewer than 10 physicians and/or other health care professionals with prescriptive privileges) primarily focused on primary care; and physicians, physician assistants, or nurse practitioners who provide primary care services in public and critical access hospitals, community health centers, rural health clinics, and in other settings that predominantly serve uninsured, underinsured, and medically underserved populations.

Provider: All providers included in the definition of "Health Care Provider" in Section 3000(3) of the Public Health Service Act (PHSA) as added by ARRA. This includes, though it is not limited to, hospitals, physicians, priority primary- care providers, Federally Qualified Health Centers (and "Look-Alikes") and Rural Health Centers.

Primary-care physician: A licensed doctor of medicine (MD) or osteopathy (DO) who practices family, general internal or pediatric medicine or obstetrics and gynecology.

Primary-Care Provider: A primary-care physician or a nurse practitioner, nurse midwife, or physician assistant with prescriptive privileges in the locality where s/he practices and practicing in one of the specialty areas included in the definition of a primary-care physician for purposes of this announcement.

ARRA-Required Performance Measures

To assist in fulfilling the accountability objectives of ARRA, as well as the Department's responsibilities under the Government Performance and Results Act of 1993 (GPRA), Public Law 103-62, applicants who receive funding under this program must provide data that measure the results of their work. Additionally, applicants must discuss their data collection methods in the application. The following are required measures for awards made under ARRA:

Objective	Performance Measures	Data the recipient provides for 3-month reporting period	Description (Plain language explanation of what exactly is being provided)
ARRA: Preserving jobs	Number of jobs saved (by type) due to ARRA funding.	a) How many jobs were prevented from being eliminated with ARRA funding during this reporting period? b) How many jobs that were eliminated within the last 12 months were reinstated with ARRA funding?	An unduplicated number of jobs that would have been eliminated if not for ARRA funding during the three-month quarter. Report this data for each position only once during the project period. A job can include full time, part time, contractual, or other employment relationship.
ARRA: Creating jobs	Number of jobs created (by type) due to ARRA funding.	How many jobs were created with ARRA funding this reporting period?	An unduplicated number of jobs created due to ARRA funding during the three month quarter. Report this data for each position only once during the award. A job can include full time, part time, contractual, or other employment relationship.

Survey Instructions on Ensuring Equal Opportunity for Applicants

Survey Instructions on Ensuring Equal Opportunity for Applicants

Applicant Organization's Name:Applicant's DUNS Number:		
Grant Name:	CFDA Number:	
	3. What is the size of the applicant's annual budget? (Check only one box.)	
1. Does the applicant have 501(c)(3) status?	☐ Less Than \$150,000	
☐ Yes ☐ No	□ \$150,000 - \$299,999	
	□ \$300,000 - \$499,999	
	□ \$500,000 - \$999,999	
2. How many full-time equivalent employees	□ \$1,000,000 - \$4,999,999	
does the applicant have? (Check only one box). $\square 3$ or $\square 15-50$	□ \$5,000,000 or more	
□ 4-5 □ 51-100		
□ 6-14 □ over 100		
	4. Is the applicant a faith-based/religious organization?	
	☐ Yes ☐ No	

	7. Has the applicant ever received a government grant or contract (Federal, State, or local)?
	□ Yes □ No
5. Is the applicant a non-religious community-based organization?	
□ Yes □ No	
	8. Is the applicant a local affiliate of a national organization?
6. Is the applicant an intermediary that will manage the grant on behalf of other organizations?	☐ Yes ☐ No
□ Yes □ No	
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Provide the applicant's (organization) name and DUNS number and the grant name and CFDA number.

- 1. 501(c)(3) status is a legal designation provided on application to the Internal Revenue Service by eligible organizations. Some grant programs may require nonprofit applicants to have 501(c)(3) status. Other grant programs do not.
- 2. For example, two part-time employees who each work half-time equal one full-time equivalent employee. If the applicant is a local affiliate of a national organization, the responses to survey questions 2 and 3 should reflect the staff and budget size of the local affiliate.
- 3. Annual budget means the amount of money your organization spends each year on all of its activities.
- 4. Self-identify.
- 5. An organization is considered a community-based organization if its headquarters/service location shares the same zip code as the clients you serve.
- 6. An "intermediary" is an organization that enables a group of small organizations to receive and manage government funds by administering the grant on their behalf.
- 7. Self-explanatory.
- 8. Self-explanatory.

Paperwork Burden Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 1890-0014. The time required to complete this information collection is estimated to average five (5) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. **If**

you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Education, Washington, D.C. 2202-4651.

If you have comments or concerns regarding the status of your individual submission of this form, write directly to: Joyce I. Mays, Application Control Center, U.S. Department of Education, 7th and D Streets, SW, ROB-3, Room 3671, Washington, D.C. 20202-4725

Privacy and Security Resources

American Reinvestment and ARRA References

ARRA Section D – Privacy describes improved privacy provisions and security provisions related to:

- o Sec. 13402 notification in the case of breach
- Sec. 13404 application of privacy provisions and penalties to business associates of covered entities
- Sec. 13405 restrictions on certain disclosures and sales of health information;
 accounting of certain protected health information disclosures; access to certain information in electronic format
- o Sec. 13406 conditions on certain contacts as part of health care operations
- Sec. 13407 temporary breach notification requirement for vendors of personal health records and other non-HIPAA covered entities
- o Sec. 13408 business associate contracts required for certain entities

This list is provided to highlight examples of the ARRA privacy and security requirements. It is not intended to be comprehensive, nor definitive program guidance to recipients regarding the ARRA requirements for privacy and security. To read a full version of ARRA, click here.

Privacy Act of 1974

 45.C.F.R. Part 5b A link to the full Privacy Act can be found at: http://www.hhs.gov/foia/privacy/index.html

HIPAA Security Rule

o 45 CFR Parts 160, 162, and 164.

A link to the HIPAA Security Rule can be found http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/adminsimpregtext.pdf.

HIPAA Privacy Rule

 45 CFR Part 160 and Subparts A and E of Part 164. For more details: http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/adminsimpregtext.pdf

Federal Information Security Management Act, 2002

o 45 CFR Parts 160, 162, and 164. A link to the full Act can be found at: http://aspe.hhs.gov/datacncl/Privacy/titleV.pdf

Confidentiality of Alcohol and Drug Abuse Patient Records

- o 45 CFR Part 2
- o For more details: http://www.hipaa.samhsa.gov

The HHS Privacy and Security Framework Principles

- Individual Access Individuals should be provided with a simple and timely means to access and obtain their individually identifiable health information in a readable form and format
- Correction- Individuals should be provided with a timely means to dispute the accuracy or integrity of their individually identifiable health information, and to have erroneous information corrected or to have a dispute documented if their requests are denied
- Openness and Transparency There should be openness and transparency about policies, procedures, and technologies that directly affect individuals and/or their individually identifiable health information.

- o Individual Choice Individuals should be provided a reasonable opportunity and capability to make informed decisions about the collection, use, and disclosure of their individually identifiable health information.
- Collection, Use and Disclosure Limitation Individually identifiable health information should be collected, used, and/or disclosed only to the extent necessary to accomplish a specified purpose(s) and never to discriminate inappropriately
- Data Quality and Integrity Persons and entities should take reasonable steps to
 ensure that individually identifiable health information is complete, accurate, and
 up-to-date to the extent necessary for the person's or entity's intended purposes
 and has not been altered or destroyed in an unauthorized manner
- Safeguards Individually identifiable health information should be protected with reasonable administrative, technical, and physical safeguards to ensure its confidentiality, integrity, and availability and to prevent unauthorized or inappropriate access, use, or disclosure
- Accountability These principles should be implemented, and adherence assured, through appropriate monitoring and other means and methods should be in place to report and mitigate non-adherence and breaches

For more information, please visit healthit.hhs.gov and click on Privacy and Security link for the Framework and its Principles, or <u>click here.</u>